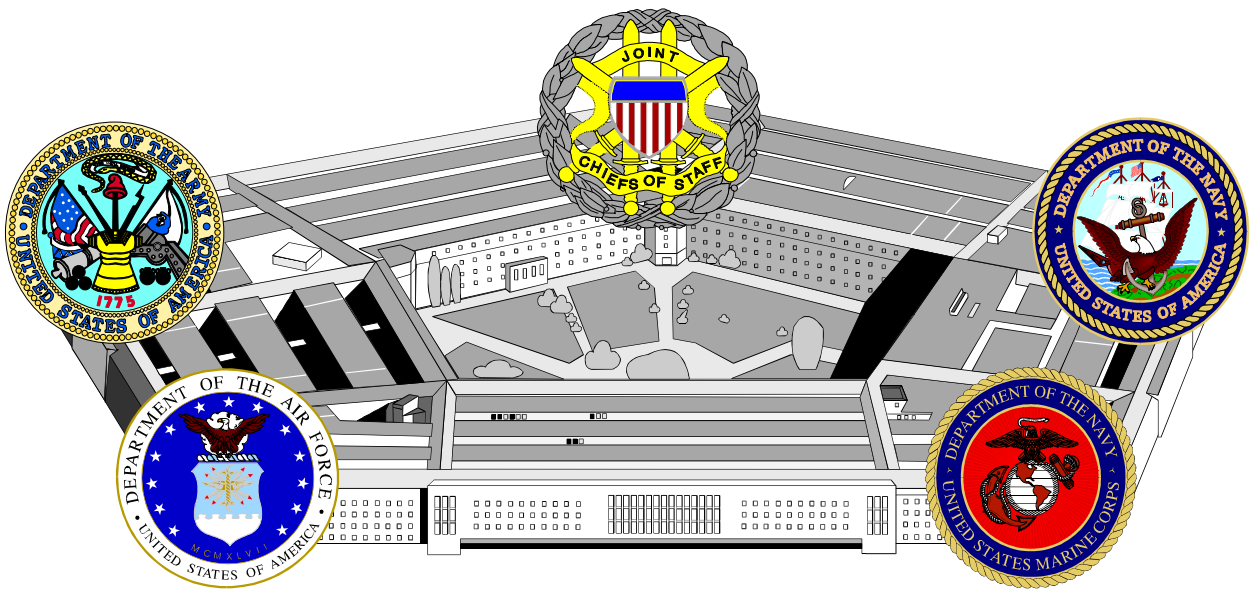
Department of Defense Chemical and Biological Defense Program



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FY2001-2003 Performance Plan

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14. ABSTRACT
This volume of the Department of Defense Chemical and Biological Defense Program Annual Report to Congress provides a performance plan and assessment for the period of FY01?FY03. This performance plan demonstrates compliance with the requirements of the Government Performance and Results Act (GPRA), which requires agencies to submit an annual performance plan to Congress. This plan establishes a process by which the CBDP can measure the effectiveness of the various projects under the CBDP and assessing their contributions to the operational goals and the mission of the program. This process provides a tool for identifying strengths and weaknesses in the development and execution of programs. This plan also will act as a reference document to aid in the effective oversight and management of the program. The plan serves the purpose of provide an assessment of the performance of the most recently completed fiscal year (FY01) and provides the performance targets against which activities conducted during FY02 and FY03 will be assessed. The data collection period for this report was October 2001 through February 2002.

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Department of Defense Chemical and Biological Defense Program FY 2001–2003 Performance Plan

1.0 INTRODUCTION

This volume of the Department of Defense Chemical and Biological Defense Program Annual Report to Congress provides a performance plan and assessment for the period of FY01–FY03. This performance plan demonstrates compliance with the requirements of the Government Performance and Results Act (GPRA), which requires agencies to submit an annual performance plan to Congress. This plan establishes a *process* by which the CBDP can measure the effectiveness of the various projects under the CBDP and assessing their contributions to the operational goals and the mission of the program. This process provides a tool for identifying strengths and weaknesses in the development and execution of programs. This plan also will act as a reference document to aid in the effective oversight and management of the program.

The plan serves the purpose of provide an assessment of the performance of the most recently completed fiscal year (FY01) and provides the performance targets against which activities conducted during FY02 and FY03 will be assessed. The data collection period for this report was October 2001 through February 2002.

For FY01, the cumulative procurement targets are based on the quantities required to support two nearly simultaneous Major Theater Wars (MTWs). However, based on the DoD 2001 Quadrennial Review, the 2 MTW requirement has been modified to support one MTW plus additional contingencies. The Joint Staff and others as conducting assessments to determine how this change affects the procurement quantities to support warfighting requirements. Moreover, the assessment for the total acquisition objective will include a determination of the quantities required to support other than warfighting requirements, including requirements for industrial base, peacekeeping, training, homeland security, or other operations.

DoD CBDP Performance Plan – Contents

Section **Page**

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1.1 OVERVIEW OF PERFORMANCE PLAN

The Department of Defense (DoD) Chemical and Biological Defense Program (CBDP) has prepared this performance plan to align itself more closely with the tenets of the Government Performance and Results Act (GPRA). Specifically, the plan:

- Establishes explicit and outcome-oriented goals linked to warfighters' ability to survive, fight, and win in a CB environment;
- Identifies quantitative and/or qualitative performance measures that can be used to assess progress towards goal achievement;
- Describes how performance data is validated;
- Describes how RDT&E activities of participating DOD and non-DOD organizations are coordinated to achieve program goals; and
- Identifies human capital, financial, and resource challenges or external factors that limit the ability of the program to achieve its goals.

The performance plan draws on information and consolidates data from reports and plans already being prepared, including:

(1) the Modernization Plan,
(2) the Research, Development, and Acquisition (RDA) Plan,
(3) the Logistics Support Plan,
(4) the Joint Warfighting Science and Technology Plan,
(5) the Defense Technology Area Plan,
(6) Joint Service Chemical/ Biological Information System (JSCBIS) materiel fact sheets, and
(7) the Annual Report to Congress.

In addition, the performance plan draws on current data contained in documents prepared in support of the PPBS, including Defense Planning Guidance, the CBDP Program Strategy Guidance, the Program Objectives Memorandum, the President's Budget and supporting detailed information in the RDT&E and Procurement Congressional Justification Books.

The major portions of this performance plan link performance goals with performance measurements in terms of those systems and programs, which support the warfighter requirements and goals. **Section 1** provides the vision, mission, goals and performance measures for the CBDP. **Section 2** analyzes performance goals and measurements that support the advanced development and acquisition phases of CB defense systems. **Section 3** analyzes the science and technology base of the program to include basic and applied research and advanced technology development, which support essential capabilities meeting warfighter requirements. Performance goals, which support each corporate level goal of the CBDP, establish a measurable path to incremental achievement of specific goals. These performance goals are supported and evaluated by measurable outputs, which are assessed using performance measures. Performance measures quantify the output of the CB defense program for key measures associated with providing a ready force, capable of conducting operations in CB contaminated environments.

1.2 VISION, MISSION, GOALS, AND VALUES OF THE CBDP

Ensure U.S. military personnel are the best equipped and best prepared force in the world for operating in future battlespaces that may feature chemically and biologically contaminated environments.

Figure 1. Chemical and Biological Defense Program Vision

This vision statement provides focus to chemical and biological defense research, development, and acquisition efforts within the CBDP. There are two key aspects of this vision statement. The first is that the focus of the CBDP is on equipping military personnel. DoD is not the lead organization with authority to develop or acquire chemical and biological defense capabilities for civilians organizations. Chapter 1 (Volume 1) of the annual report describes some of the cooperative activities that DoD participates in to support CB defense homeland security needs. The other key aspect of the vision statement is "operating in future battlespaces." While the vision statement has not been revised in light of the terrorist attacks of September 11, 2001 or the anthrax-contaminated letters in 2001, DoD recognizes the changing threat environment, factors, and conditions that must be understood to successfully apply combat power, protect the force, or complete the mission. The definition of future battlespaces is being broadened to incorporate not only traditional military operations on the battlefield and foreign deployments, but it will also incorporate increasing roles in support of homeland security within the United States.

The *Quadrennial Defense Review Report*, September 2001, serves as the overall strategic planning document of the Department. For FY01, the requirements were based on supporting two nearly simultaneous Major Theater Wars (MTWs). The Quadrennial Defense Review (QDR) defines a new force-sizing construct, which replaces the 2 MTW construct. This new force-sizing construct specifically shapes forces to:

- Defend the United States;
- Deter aggression and coercion forward in critical regions;
- Swiftly defeat aggression in overlapping major conflicts while preserving for the President the option to call for a decisive victory in one of those conflicts - including the possibility of regime change or occupation; and
- Conduct a limited number of smaller-scale contingency operations.

In doing so, DoD will maintain sufficient force generation capability and a strategic reserve to mitigate risks.

In order to support the QDR force-sizing construct and to implement to program vision, **Figure 2** defines the mission for the Chemical and Biological Defense Program. Over the next year, the Department will review this mission and the supporting operational goals to address its evolving role in combating terrorism and homeland security.

Provide world-class chemical and biological defense capabilities to allow the military forces of the United States to survive and successfully complete their operational missions across the entire spectrum of conflict—from peacetime contingency missions through overlapping major conflicts—in environments contaminated with chemical or biological warfare agents.

Figure 2. Chemical and Biological Defense Program Mission

A key element in providing a means to establish progress in fulfilling the program mission is the definition of corporate goals for the CBDP, as shown in **figure 3**. Corporate goals provide the broad warfighter requirements for NBC defense operations. These operational goals provide direction for the development, acquisition, and fielding of NBC defense equipment. The CBDP thus develops, acquires, and fields equipments that meets warfighter requirements while reducing acquisition costs and time of development. Figure 3 defines the corporate operational goals (and provides a summary of the key materiel capabilities that support these goals.)

- **View NBC Warfare Agents within the Theater Area of Operations**
  (Early Warning and Stand-off Detection of NBC Agents)
- **Dominate the Battlespace through Reconnaissance, Surveillance, and Target Acquisition (RSTA)**
  (NBC Reconnaissance Systems)
- **Enhance the Situational Awareness of Unit Battlespace**
  (Expanded Sensor Capability of Automatic Point and Remote Detection of NBC Agents)
- **Provide Real-Time Hazard Information to Influence Current Operations**
  (NBC Battle Management, Warning & Reporting, and Modeling & Simulation)
- **Enhance Personnel and Equipment Survivability**
  (Individual Detection, Individual Protection, Medical defenses, Decontamination, and NBC Contamination Survivability)
- **Maintain Ground, Air and Maritime Operational Tempo**
  (Operational Decontamination and Mobile Collective Protection)
- **Sustain Operations, Recovery and Reconstitution Efforts**
  (Thorough Decontamination, Fixed Site Collective Protection, Medical Diagnosis and Treatment, Training, and Readiness)

Figure 3. Chemical and Biological Defense Program Corporate Goals

Chemical/Biological Defense Program Values

In order to carry out the mission of the CBDP, criteria and processes to guide the methods in which the goals and mission will be pursued have been defined. As stated in the QDR, the general policy objectives of the Department of Defense, which are to:

(1) assure allies and friends,
(2) dissuade future military competition,
(3) deter threats and coercion against U.S. interests, and
(4) if deterrence fails, decisively defeat any adversary.

These policy objectives are described in detail in the QDR Report. These defense policy goals are supported by an interconnected set of strategic tenets. It is only through careful attention and commitment to each of these tenets that the defense policy goals will be achieved. These tenets comprise the essence of U.S. defense strategy, and include:

- *Managing risks* — DoD must prepare for future challenges over time, while meeting extant threats at any given time.

- *A capabilities-based approach* — focuses more on how an adversary might fight than who the adversary might be and where a war might occur. It broadens the strategic perspective and requires identifying capabilities that U.S. military forces will need to deter and defeat adversaries who will rely on surprise, deception, and asymmetric warfare to achieve their objectives.
- *Defending the United States and Projecting U.S. Military Power* — restores the emphasis once placed on defending the United States and its land, sea, air, and space approaches.
- *Strengthening Alliances and Partnerships* — requires that U.S. forces train and operate with allies and friends in peacetime as they would operate in war.
- *Maintaining favorable regional balances* — secure peace, extend freedom, and assure its allies and friends.
- *Developing a broad portfolio of military capabilities* — to create substantial margins of advantage across key functional areas of military competition to prevail over current challenges and to hedge against and dissuade future threats.
- *Transforming defense* — a continuing process to reduce cost and leverage opportunities in order to be prepared to meet emerging challenges.

Values are the principles, standards, and qualities the CBDP organization follows to accomplish the mission, achieve the goals and attain the vision. They direct the size, focus, and coordination of the program—not program outcomes. The values provide statements that identify both the ways and means of the program and also consequences of the program that may result from the successful accomplishment of program goals and missions.

- ***Deter the use of chemical and biological warfare agents.***
  – Deny the advantage of the potential effective use of chemical or biological warfare agents by an initiator through a system of capabilities to avoid, protect against, and sustain operations in a contaminated environment —with only minimal performance degradation from either the effects of the agents or any protective equipment or medical countermeasures.

- ***Ensure all capabilities provided respond to validated threats.***
  – Provide capabilities that address the highest priority CB agent threats, from immediate and validated threats through potential far term or emerging threats. Intelligence efforts must emphasize preparation of tailored intelligence documents that identify and assess threats from the full spectrum of potential chemical and biological warfare agents, and include collection and analysis of nations' "dual-use" chemical and biological industrial capabilities and the indications and warning of adversarial use of dual-use capabilities. Tailored intelligence documents are essential for assessing, developing and updating requirements for CB defense programs.

- ***Provide capabilities to ensure that the warfighter can survive in a chemical or biological environment and complete all operational and support missions.***
  – Provide capabilities that support the prioritized needs of the warfighter and requirements outlined in the Defense Planning Guidance and National Military Strategy.

- ***Maintain technological advantage over any potential adversaries and prevent technological surprise.***

– Evaluate and leverage continuous improvements in the state-of-the-art in sciences and technologies.

- ***Emphasize a Joint Service approach to chemical and biological defense research, development, and acquisition.***
  – Eliminate unnecessary redundancies among the Services and Defense Agencies, leverage common technologies and requirements, and provide capabilities for Service-unique missions. Ensure coordination among U.S. government agencies and among U.S. allies to field the best available chemical and biological defense capabilities.
- ***Participate in international cooperative and collaborative efforts to leverage technology development and to achieve commonality, interoperability, and systems integration among U.S. allies and coalition partners.***
- ***Provide the most up-to-date doctrine and tactics, techniques, and procedures to solve deficiencies and for the employment of newly developed materiel.***
  – Provide guidance to the warfighter on proper operating procedures utilized in a chemical and/or biological environment.
- ***Provide the best training opportunities to ensure the readiness of the Force to fight in an asymmetric environment.***
  – Ensure that the development of new equipment includes embedded simulation and training capabilities.
- ***Complete critical RDT&E and acquisition of improved chemical and biological detection, identification and warning systems, individual and collective protection systems, medical support and decontamination systems.***
  - Ensure that the warfighter's needs are met in a timely fashion by improving the capabilities of existing equipment and technologies.
- ***Provide for a responsive medical modernization strategy to prevent CB casualties or treat them when prevention is impossible so they can return to duty.***
  - Develop effective medical countermeasures to include prophylaxes/pretreatments, diagnostics, therapeutics, and vaccines.

1.3 PERFORMANCE PLAN METHODOLOGY

Data Analysis

In order to measure the performance of individual programs within the overall Chemical and Biological Defense Program (CBDP), programs are assessed to determine how each actually performed in comparison to the stated program targets. The specific targets represent the program objectives for each year. **Figure 4** illustrates the sources of information that allow a comparison over time. As illustrated, the *targets* for each fiscal year (FY) are derived for that year's corresponding President's Budget Submission to Congress. The accomplishments are reported in the President's Budget Submission immediately following the completion of that fiscal year. Thus, the FY03 President's Budget Submission includes FY01 Accomplishments and FY03 Targets.

This methodology provides a means of ensuring accurate data reporting. Where targets are met, this is stated as "targets met" rather than repeating the targets. Where program accomp-

lishments may be at variance with program targets, the differences are explained. Variances do not necessarily mean poor performance. Variances may occur as a result of schedule changes in supporting programs, changes in funding, or unexpected test results.

When changes are made to a program after the budget is submitted, changes are explained following the completion of that fiscal year. This allows for a fair comparison by providing a detailed description of accomplishments and the variance from the targets. Targets are not changed to reflect accomplishments. Thus, for example, emergency supplemental funds added to the FY02 budget to support efforts to combat terrorism result in changes to the FY02 targets. However, since these changes occurred after the FY02 President's Budget was submitted, the additional resources and targets will be explained in the FY02 accomplishments.

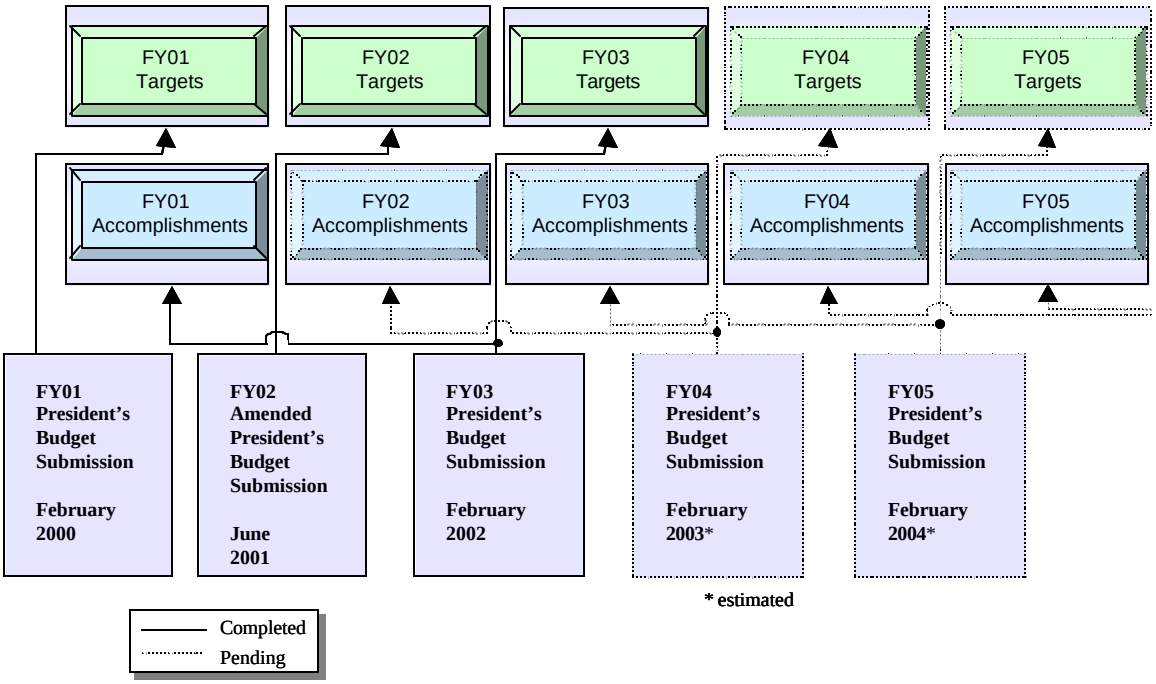

Figure 4. Performance Plan Methodology

Performance Analysis

Analysis of program data is only part of the assessment process. The next step in the assessment is a comparison of the results of the data analysis against performance goals, corporate goals, and the overall CBDP mission.

The CBDP mission is stated in Section 1.2.2. The CBDP Operational Goals are stated in section 1.2.4. Operational goals identified by the Services and Warfighting Commanders-in-Chief (CINCs). These goals support the program mission and provide a framework for measuring progress of the various programs under the CBDP in supporting the mission. The operational goals are derived from the *Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan*. In order to provide a link between programs and operational goals, supporting performance goals are developing in coordination with the Joint Staff. Supporting performance goals, detailed in section 2.3, establish a measurable path to incremental achievement of specific

operational goals. **Figure 5** illustrates the relationship between the CBDP mission and specific programs.

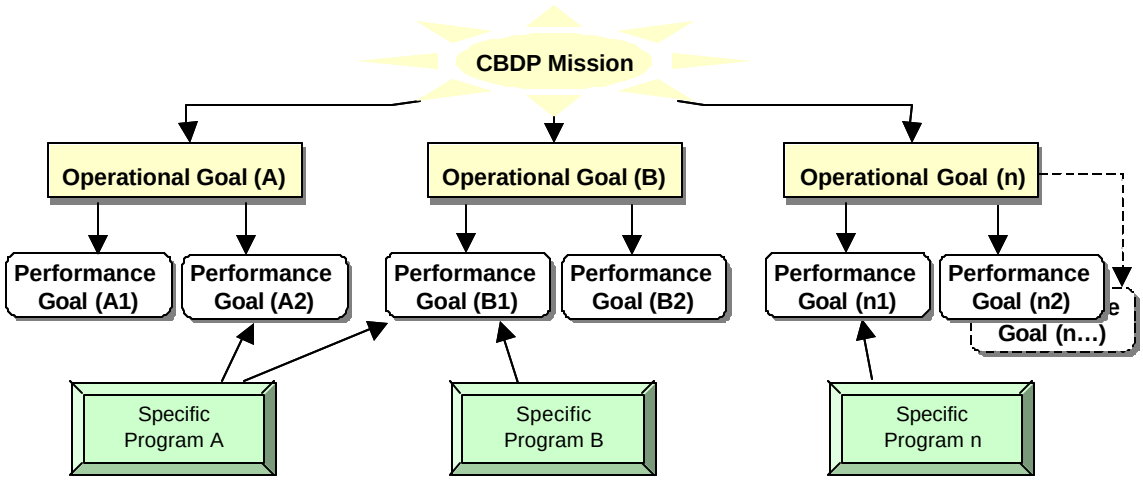

Figure 5. Conceptual Relationship between CBDP Mission and Programs

There are several principles illustrated by this figure:

- Performance goals are driven by and derived from operational goals (which in turn are derived from the program mission.)
- Performance goals are *supported by* programs.
- All funded programs should support a performance goal. (The only exception is for supporting technologies, which are necessary for the development or execution of a program.)
- A program may support more than one performance goal.
- Multiple programs supporting the same performance goal can be evaluated to determine complementarities, synergies, or redundancies.
- Not all performance goals may be supported by a program. This may be the result of the development of a new mission or operational goal, or from the lack of an available technology.
- Programs that do not support a performance goal cannot be demonstrated to support the program mission and may reflect an inappropriate use of resources.

In stating this latter principle, it is important to note that performance measures are *not* operational requirements. Rather, performance measures provide an analytic framework by which programs and operational goals may be linked. **Figure 6** shows the specific relationship between the CBDP mission and performance measures.

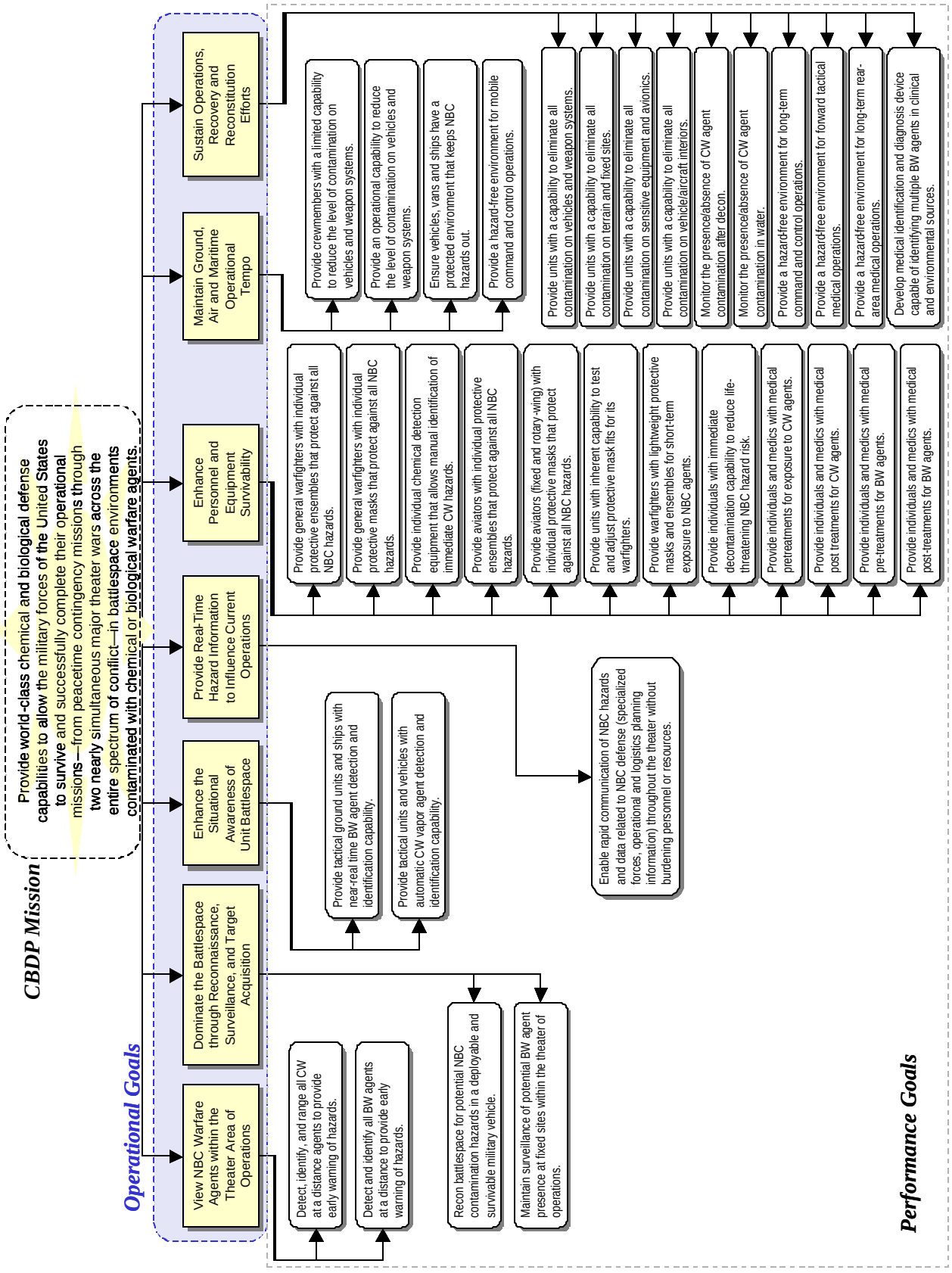

Figure 6. Relationship between CBDP Mission and Performance Measures

2.0 ADVANCED DEVELOPMENT AND ACQUISITION PERFORMANCE GOALS AND MEASURES

The following sections provide near-term performance goals, performance measures, and targets which support program corporate level goals. For the purpose of this strategy plan, FY2001 is the current assessment year, for which actual performance can be assessed; FY 2002 and FY 2003 are the future assessment years for which targets are established, and will be assessed in future annual performance plans. Future material solutions refer to those that will be addressed during years cited, some of which may be in the technology base.

2.1 Metric Description

Research, Development and Acquisition (RDA) programs within the DoD CBDP aim to ensure that U.S. forces are provided with the best equipment, which will ensure survivability and mission accomplishment on any future battlefield where chemical or biological agents are employed. The increased complexity of modern warfare demands that CB defense equipment be fielded in the most cost effective and expeditious manner possible. Additionally, the evolving threat environment requires a capabilities-based approach, which requires identifying capabilities that U.S. military forces will need to defend against adversaries since specific adversary's intentions may not be possible to determine. Specific materiel solutions are identified which support numerous Commander-In-Chief (CINC) requirements. Each materiel solution's progress is measured by monitoring specific performance goals and targets in the planning years. Each of these metrics supports the ultimate objective; that of fielding new and improved CB defense equipment to our warfighting forces.

2.2 Verification and Validation (V&V) of Metrics

V&V is accomplished through a number of processes. First and foremost, the Planning, Programming, and Budgeting System (PPBS) is the key process employed by the DoD CBDP and is used to ensure that program performance goals and targets are implemented into its budget. Through the PPBS, the program apportions resources annually in support of the goals articulated in the planning process.

Each year the Deputy Assistant to the Secretary of Defense of Chemical/Biological Defense, DATSD(CBD), issues detailed planning guidance in the DoD CBDP Program Strategy Guidance, which is used by the Joint NBC Defense Board (JNBCDB) in formulating and preparing the Program Objective Memorandum (POM). This document serves as a strategic planning document, and provides a framework for assessment of the POM and how well it meets stated goals and targets. In conjunction with the publication of the POM, the Joint NBC Board develops an assessment of how well the goals are met. The OSD staff in turn assesses these goals, as the POM is reviewed and adjusted through the summer review process. Preparation of the Budget Estimate Submission (BES) in the fall, begins a new review process, culminating in the finalization of the President's Budget for the DoD CBDP. The PPBS process is an effective mechanism for the DATSD(CBD) to match corporate CB defense goals and targets with the appropriate budgetary resources in a fiscally constrained environment.

In addition to the annual PPBS process, the DoD CBDP relies on an oversight process, which permits reviews of program status on a monthly basis through staff review of JSCBIS Information Sheets. System PMs and item managers prepare quarterly system summary sheets,

which are reviewed by the OSD staff. Selected systems are then selected for review at quarterly In-Process-Reviews held for senior leadership of the DoD CBDP.

Another V&V mechanism used by the CBDP is the Annual Report to Congress. During preparation of the report, the CB defense community reports annual progress within the various facets of the program. Annual accomplishment and plans for the future, as well as issues and factors that limit the ability of the program to achieve its goals, are documented and summarized along with the President's Budget.

2.3 CBDP Corporate Goals and Supporting Performance Goals

This section identifies each Corporate Goal and supporting performance goals. Corporate Goals are key operational objectives of the warfighters, which are identified as CINC Requirements in *The Joint Service NBC Defense RDA Plan*. Performance goals are key objectives or capabilities that, if achieved, will support attainment of the Corporate Goals. Performance goals are not specific projects or programs. Because the CBDP is established to coordinate and integrate RDA programs for chemical and biological defense within the Department, the key performance measures for the performance goals are specific projects and programs, including the cost and schedule of key programs, as well as the performance of the systems in achieving the objective and required performance parameters as defined in requirements documents and the number of systems fielded. Based on the specific system identified, there are some projects and systems that may support multiple performance goals or corporate goals. These performance measures are similar to performance measures used in other DoD GPRA performance plans.

Additional performance measures include non-material solutions for achieving goals. Non-material solutions include, among other things, training, doctrine, and sustained logistics capabilities. These additional efforts may be included as performance measures in future performance plans. Information and specific data on these efforts may be found in the Annual CBDP Report in Chapter 3 (Logistics) and Chapter 4 (Doctrine, Training, and Readiness). For purposes of this initial performance plan, performance measures focus on the core effort of the CBDP—that is, RDA programs and systems. The success of the CBDP is measured based on the ability to provide systems and capabilities to the U.S. forces so that they may achieve their operational objectives in a contaminated environment. For each performance goal the current materiel solution and the projected future materiel solution is listed. These systems are assessed for progress towards meeting targets. In some cases, current materiel solutions are legacy systems, which means that all planned procurement is complete and these systems will not have any procurement targets to assess.

The following tables provide a summary of all Corporate Goals and their supporting performance goals. (Note: the goal numbers are provided for reference purpose and may not indicate priority.)

2.3.1 Corporate Goal 1

Corporate Goal 1: View NBC Warfare Agents within the Theater Area of Operations

Supporting Performance Goals:

1.1 Detect, identify, and range all CW at a distance agents to provide early warning of hazards.

1.2 Detect and identify all BW agents at a distance to provide early warning of hazards.

2.3.2 Corporate Goal 2

Corporate Goal 2: Dominate the Battlespace through Reconnaissance, Surveillance, and Target Acquisition (NBC Reconnaissance)

Supporting Performance Goals:

2.1 Recon battlespace for potential NBC contamination hazards in a deployable and survivable military vehicle.

2.2 Maintain surveillance of potential BW agent presence at fixed sites within the theater of operations.

2.3.3 Corporate Goal 3

Corporate Goal 3: Enhance the Situational Awareness of Unit Battlespace

Supporting Performance Goals:

3.1 Provide tactical ground units and ships with near-real time BW agent detection and identification capability.

3.2 Provide tactical units and vehicles with automatic CW vapor agent detection and identification capability.

2.3.4 Corporate Goal 4

Corporate Goal 4: Provide Real-Time Hazard Information to Influence Current Operations (NBC Battle Management and Modeling & Simulation)

Supporting Performance Goal:

4.1 Enable rapid communication of NBC hazards and data related to NBC defense (specialized forces, operational and logistics planning information) throughout the theater without burdening personnel or resources.

2.3.5 Corporate Goal 5

Corporate Goal 5: Enhance Personnel and Equipment Survivability (Individual Detection/Protection/Decon)

Supporting Performance Goals:

5.1 Provide general warfighters with individual protective ensembles that protect against all NBC hazards.

5.2 Provide general warfighters with individual protective masks that protect against all NBC hazards.

5.3 Provide individual chemical detection equipment that allows manual identification of immediate CW hazards.

5.4 Provide aviators with individual protective ensembles that protect against all NBC hazards.

5.5 Provide aviators (fixed and rotary-wing) with individual protective masks that protect against all NBC hazards.

5.6 Provide units with inherent capability to test and adjust protective mask fits for its warfighters.

5.7 Provide warfighters with lightweight protective masks and ensembles for short-term exposure to NBC agents.

5.8 Provide individuals with immediate decontamination capability to reduce life-threatening NBC hazard risk.

5.9 Provide individuals and medics with medical pretreatments for exposure to CW agents.

5.10 Provide individuals and medics with medical post treatments for CW agents.

5.11 Provide individuals and medics with medical pre-treatments for BW agents.

5.12 Provide individuals and medics with medical post-treatments for BW agents

2.3.6 Corporate Goal 6

Corporate Goal 6: Maintain Ground, Air and Maritime Operational Tempo (Operational Decon/Collective Protection)

Supporting Performance Goal:

6.1 Provide crewmembers with a limited capability to reduce the level of contamination on vehicles and weapon systems.
6.2 Provide an operational capability to reduce the level of contamination on vehicles and weapon systems.
6.3 Ensure vehicles, vans and ships have a protected environment that keeps NBC hazards out.
6.4 Provide a hazard-free environment for mobile command and control operations.

2.3.7 Corporate Goal 7

Corporate Goal 7: Sustain Operations, Recovery and Reconstitution Efforts (Thorough Decontamination, Fixed Site Collective Protection, Medical Diagnosis and Treatment, Training, and Readiness)

Supporting Performance Goals:

7.1 Provide units with a capability to eliminate all contamination on vehicles and weapon systems.
7.2 Provide units with a capability to eliminate all contamination on terrain and fixed sites.
7.3 Provide units with a capability to eliminate all contamination on sensitive equipment and avionics.
7.4 Provide units with a capability to eliminate all contamination on vehicle/aircraft interiors.
7.5 Monitor the presence/absence of CW agent contamination after decon.
7.6 Monitor the presence/absence of CW agent contamination in water.
7.7 Provide a hazard-free environment for long-term command and control operations.
7.8 Provide a hazard-free environment for forward tactical medical operations.
7.9 Provide a hazard-free environment for long-term rear-area medical operations.
7.10 Develop medical identification and diagnosis device capable of identifying multiple BW agents in clinical and environmental sources.

2.4 CORPORATE GOAL 1: VIEW NBC WARFARE AGENTS WITHIN THE THEATER AREA OF OPERATIONS *(STAND-OFF DETECTION OF NBC AGENTS)*

2.4.1 *Performance Goal 1.1* – Detect, identify, and range all CW agents at a distance to provide early warning of hazards.

Current Materiel Solutions	Future Materiel Solutions
M21 Remote Sensing Chemical Agent Alarm (RSCAAL) (Legacy System) AN/KAS-1, Chemical Warfare Directional Detector (Legacy System)	Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD) Joint Service Chemical Warning and Identification LIDAR Detector (JSWILD), *program also called ARTEMIS* Chemical Imaging Sensor SAFEGUARD

2.4.2 Materiel Solutions Performance Measurements.

2.4.2.1 Current Procurement Targets – JSLSCAD

	FY01		FY02	FY03
Systems	Target	Actual	Target	Target
JSLSCAD	0 [0 of 1,929 procured]	0 [0 of 1,929 procured]	70	0

2.4.2.2 Current Research & Development (R&D) Targets – *JSLSCAD*

FY 2001 Targets	Actual Performance
- Continue integration for test platform - EDT test review and modify design based on EDT test review - Fabricate 47 PQT/IOT&E test articles - Conduct PQT/IOT&E which includes environmental extremes, shock and vibration, EMI, EMP, agent, and shipboard, helicopter, airplane, and ground vehicle field testing - Prepare tech data package and documentation for JS MS III decision in FY02	- Program rebaselined: MS III changed to FY04 due to test scope increases and contract schedule extension. - Initiated the integration for the Joint Service Lightweight Nuclear, Biological, Chemical Reconnaissance System (JSLNBCRS), CH-53 helicopter, and C-130 fixed wing test platforms - Completed Engineering Design Test (EDT). Reviewed and modified system design to incorporate test review results - Initiated the fabrication of 35 Production Qualification Testing/Initial Operation Test & Evaluation (PQT/IOT&E) Test Articles - Initiated PQT/IOT&E which includes environmental extremes, shock and vibration, Electromagnetic Interference (EMI), Electromagnetic Pulse (EMP), agent and shipboard, helicopter, airplane, and ground vehicle field testing - Initiated the preparation and review of technical data package and acquisition documentation

2.4.2.3 Future R&D Targets – *JSLSCAD*

FY 2002 Targets	FY 2003 Targets
- Complete PQT and IOT&E - Complete technical data package and documentation for Milestone III. All program documentation will be reviewed and updated to support MS III. This includes: Acquisition Strategy, Acquisition Baseline, Performance Specifications, and Environment Assessment. IPR package preparation and coordination is also included. - Complete review and preparation of technical manuals, logistics support, and training materials. All logistics documentation to include: Technical Manuals; Integrated System Support Plans; and Logistics Support Plans will be updated based on test results. In addition, Materiel Fielding Plans, fielding schedules, and platform integration guides will be prepared and approved.	- Complete PQT/IOT&E (35 Test Articles) - Complete technical data package and acquisition documentation for Milestone III. All program documentation will be reviewed and updated to support MS III. This includes: Acquisition Strategy, Acquisition Baseline, Performance Specifications, and Environment Assessment. IPR package preparation and coordination is also included. - Continue the review and preparation of technical manuals, logistics support, and training manuals. All logistics documentation to include: Technical Manuals; Integrated System Support Plans; and Logistics Support Plans will be updated based on test results. In addition, Materiel Fielding Plans, fielding schedules, and platform integration guides will be prepared and approved.

2.4.2.4 Current R&D Targets – JSWILD (Artemis)

FY 2001 Targets	Actual Performance
- Perform program planning and execution of project management functions. Prepared for and develop MSI program documentation and coordinate program with Joint Service Integrated Product Team representatives - Conduct studies to validate technology alternatives. Contract preparation and Request for Proposal release for prototype development contract award in FY02. - Analyze and translate ORD; complete Analysis of Alternatives; develop draft performance specification; finalize MSI documentation and obtain MSI approval	- Completed Analysis of Alternatives (including modeling and simulation) to validate technology alternatives. Completed Independent Total Ownership Cost (TOC) Analysis. - Supported initiation of the Joint Service Integration Group (JSIG) Contamination Avoidance Mission Needs Analysis. - Initiated program acquisition strategy and documentation. Joint Analysis of Alternatives Integrated Product Team provided support, oversight, and coordination.

2.4.2.5 Future R&D Targets – JSWILD (Artemis)

FY 2002 Targets	FY 2003 Targets
- Complete performance specification and update Acquisition Program Baseline and C^4ISR Support Plan. Prepare source documentation for MS B. Maintain document library and information network for all data, research, and other program information. Finalize and issue RFP, conduct source selection for prototype development contractor, conduct review of draft system work breakdown structure, preliminary functional baseline, and draft systems specification. - Finalize Systems Architecture and Systems Specification through a Joint Systems Engineering IPT. Analyze the ORD and develop performance specifications for prototype development. Conduct risk analyses. - Update Simulation Based Acquisition Strategy and Simulation Support Plan to identify the effective use of modeling and simulation throughout the system life cycle. Update/validate the virtual prototype model to support design of early prototype	- Complete source documentation for MS B. Finalize and issue RFP, conduct source selection, award contract for System Development and Demonstration (SDD) prototypes. - Conduct Integrated Baseline Review (IBR) and System Requirement Review (SRR) with SDD contractor. - Initiate design, build, and integration of SDD prototypes for use in developmental testing - Initiate design, documentation, development of Artemis system software. In addition, initiate effort to develop interface between Artemis and (Joint Warning and Reporting Network.

FY 2002 Targets	FY 2003 Targets
system. Update cost model to reflect new system architecture. Evaluate infrared spectra scene generator equipment in support of virtual testing. - Conduct a supportability analysis. Conduct initial Joint Training Planning Process Methodology and develop initial Joint System Training Plan. Develop acquisition logistics support plan for Milestone B through a Joint Logistics/Product Support IPT. - Develop test methodology in support of the test strategy and finalize initial Test & Evaluation Master Plan for Milestone B through a Joint Test & Evaluation IPT. - Further develop components of LIDAR system for a systems architecture and to reduce overall risk by utilizing Advance Component Development. Perform testing on high-risk components to validate performance.	- Develop detailed test support plan. Purchase additional equipment to support range and chamber testing of a long-range active LIDAR standoff detection system.

2.4.2.6 Current R&D Targets – Chemical Imaging Sensor and SAFEGUARD

FY 2000 Targets	Actual Performance
- Programs in technology base	See section 3.0: S&T Performance Goals & Measures

2.4.3 *Performance Goal 1.2* – Detect and identify BW agents at a distance to provide early warning of hazards.

Current Materiel Solutions	Future Materiel Solutions
Long Range- Biological Standoff Detection System (LR-BSDS)	Joint Biological Standoff Detection System (JBSDS)

2.4.4 Materiel Solutions Performance Measurements.

2.4.4.1 Current Procurement Targets – LR-BSDS

	FY01		FY02	FY03
System	Target	Actual	Target	Target
Long Range-Biological Standoff Detection System (LR-BSDS)	3 LR-BSDS NDI systems have been fielded	*Program cancelled in FY 00 due to change of user requirement*	*n/a*	*n/a*

2.4.4.2 Current R&D Targets – JBSDS

FY 2001 Targets	Actual Performance
- Initiate the Advanced Component Development of JBSDS Block I candidates	- Target met

2.4.4.3 Future R&D Targets – JBSDS

FY 2002 Targets	FY 2003 Targets
- Complete system development and integration of the lightweight, early warning JBSDS system - Initiate testing of the integrated, lightweight early warning system	- Transition early warning standoff systems developed in the TT-Bio program into the Systems Integration phase of the JBSDS program - Conduct developmental testing of JBSDS competing candidate systems - Initiate limited operational testing and assessment of JBSDS competing candidate systems

2.5 CORPORATE GOAL 2: DOMINATE THE BATTLESPACE THROUGH RECONNAISSANCE, SURVEILLANCE, AND TARGET ACQUISITION *(NBC RECONNAISSANCE)*

2.5.1 *Performance Goal 2.1* – Recon battlespace for potential NBC contamination hazards in a deployable and survivable military vehicle.

Current Materiel Solutions	Future Materiel Solutions
M93A1 NBC Recon System (Block I) Biological Integrated Detection System	M93A1 NBC Recon System (Block II) Joint Light NBC Recon System (HMMWV/LAV)

2.5.2 Materiel Solutions Performance Measurements.

2.5.2.1 Current Procurement Targets – NBCRS (Block I)

	FY01		FY02	FY03
Systems	Target	Actual	Target	Target
M93A1 NBC Recon System (Block I)	33 95 of 123 procured	33 95 of 123 procured	5	0

2.5.2.2 Current R&D Targets – NBC Reconnaissance System, Block II (M93A1)

FY 2001 Targets	Actual Performance
- Fabricate four prototype systems - Complete engineering and logistics documentation - Conduct system test and evaluation	None of the targets met. FY 2001 accomplishments: - Continued sensor suite engineering development and acquisition of detectors - Initiated plans for Developmental Test and Evaluation - Continued software development - Initiated design for assembly and integration of developmental detectors into vehicles

2.5.2.3 Future R&D Targets – NBC Reconnaissance System, Block II (M93A1)

FY 2002 Targets	FY 2003 Targets
- Conduct modeling and simulation of human factors - Continue sensor suite engineering development and refurbish prototypes - Continue integration of developmental detectors into vehicles - Begin warfighter operational capability assessment	- Complete NBCRS sensor suite engineering development and conduct Interim Progress Review to begin Low Rate Initial Production phase - Complete PQT & Early User Test.

2.5.2.4 Current R&D Targets – Joint Lightweight NBC Reconnaissance System, HMMWV/LAV variants (JSLNBCRS)

FY 2001 Targets	Actual Performance
- Complete technical data package and requisite acquisition documentation for MS III - Complete Operational Testing	None of the targets met. FY 2001 accomplishments: - Built/integrated two M1113 HMMWV variants - Completed DT I for two M1113 HMMWV variants

2.5.2.5 Future R&D Targets – JSLNBCRS

FY 2002 Targets	FY 2003 Targets
- Start IOT&E - Continue LUT of HMMWV variant at the US Army Test Activity - Start software and hardware engineering development and integration of commercial off the shelf, government off the shelf software, hardware, and non-developmental item software hardware products to the maximum extent possible for HMMWV & LAV variants - Continue Developmental Test II at Dugway and Yuma Proving Grounds - Initiate TIC and TIM software development for CBMS transition to JSLNBCRS procurement	- Start DT I for LAV variant - Complete development of TICs and TIMs software for CBMS transition to JSLNBCRS procurement - Conduct DT III for LRIP HMMWV variants - Start IOT&E for LAVs and HMMWVs for full rate production/Milestone C

2.5.3 *Performance Goal 2.2* – Maintain surveillance of potential BW agent presence at fixed sites within the theater of operations.

Current Materiel Solutions	Future Materiel Solutions
Portal Shield Biological Integrated Detection System (BIDS)	Joint Biological Point Detection System (JBPDS)—Block I, and II

2.5.4 Materiel Solutions Performance Measurements.

2.5.4.1 Current Procurement Targets – Portal Shield, BIDS, and JBPDS

Systems	FY01		FY02	FY03
	Target	Actual	Target	Target
Portal Shield	97 [97 of 97 procured]	97 [97 of 97 procured]	*n/a*	*n/a*
Biological Integrated Detection System	0 [124 of 124 procured]	14 [138 of 124 procured]	*n/a*	*n/a*
Joint Biological Point Detection System	143 [143 of 1,997 procured]	5 [5 of 1,997 procured]	16	133

2.5.4.2 Current R&D Targets – Joint Biological Point Detection System

FY 2001 Targets	Actual Performance
Block I Program: - None. Program to transition to procurement in FY 2001.	Program did not transition to procurement in FY 2001. FY 2001 accomplishments: - Conduct Operational Assessment II and supported Block I IOT&E planning required for a MSIII decision - Conducted Risk Reduction and initiated Product Improvements on system suite and the BAWS detector design

FY 2001 Targets	Actual Performance
Block II Program: - Continue hardware/software development, ruggedization, test and evaluation of biological detection components. Focus will be on JBPDS Block II candidate components and legacy system upgrades, which will improve detection time and reduce operating consumables - Initiate common Biological Suite Enhancement Design Engineering efforts. These efforts include reducing system size and weight, as well as development and integration of advanced "dry" detection/identification technologies to reduce life cycle costs and logistics demands	Targets not met. - Initiate modeling, design, fabrication, and test of next generation BAWS prototype - Initiated Block II design studies to define performance specifications, identify potential design concepts, and reduce risk to the EMD program - Initiated preparations of the RFP for Block II EMD contract *Justification*: New Acquisition Strategy directed by JSMG and lack of technology advancements - MS B to be delayed until FY03 - FY01 design studies limited to the identification of new concepts - RFP for System Design and Demonstration (SDD) delayed until FY03.

2.5.4.3 Future R&D Targets – Joint Biological Point Detection System

FY 2002 Targets	FY 2003 Targets
Block I Program - Initiate IOT&E (Army at Dugway Proving Grounds)	Block I Program - Complete Army IOT&E and reporting - Initiate USAF, USMC and Navy IOT&E
Block II Program: - Initiate software development and documentation. Develop advanced algorithms that will enhance the JBPDS Block II ability to discriminate background environment aerosol components, while not sacrificing its sensitivity and responsiveness to biological warfare attacks - Initiate early integrated logistics support to ensure the lowest possible life cycle costs and supportablility of the Block II system in the field - Initiate component selection, fabrication, and evaluation to develop and refine the critical components of the Block II that will give the system the performance capabilities required in the JORD - Initiate system level hardware development, integration, evaluation, and documentation to ensure that individual components can be successfully integrated into a functioning, coordinated system to meet system automation, and ensure component compatibility - Support a joint field trial conducted to identify technologies - Support the hardware selection, fabrication, and evaluation efforts necessary to develop and refine the critical components that will ensure the JBPDS Block II system meets the performance capabilities required by the JORD	Block II Program: - Develop software and hardware advances to BAWS algorithms that will provide increased reliability and enhance the JBPDS Block II ability to discriminate background environment aerosol components, without sacrificing sensitivity and responsiveness to biological warfare attacks - Establish core and Joint Service IPTs and initiate product improvements of Line Replaceable Units, through design, procurement, fabrication, and critical item testing

2.6 CORPORATE GOAL 3: ENHANCE THE SITUATIONAL AWARENESS OF UNIT BATTLESPACE – *(AUTOMATIC POINT DETECTION OF NBC AGENTS)*

2.6.1 *Performance Goal 3.1* – Provide tactical ground units and ships with near-real time BW agent detection and identification capability.

Current Materiel Solutions	Future Materiel Solutions
None	Joint Biological Point Detection System (JBPDS)

2.6.2 Materiel Solutions Performance Measurements – (JBPDS) (see 2.5.4.1)

2.6.3 *Performance Goal 3.2* – Provide tactical units and vehicles with automatic CW vapor agent detection and identification capability.

Current Materiel Solutions	Future Materiel Solutions
M8A1 Chemical Agent Alarm (Legacy) M22 ACADA Improved (CA) Point Detection System (IPDS)	Joint Chemical Agent Detector (JCAD)

2.6.4 Materiel Solutions Performance Measurements

2.6.4.1 Current Procurement Targets – M22 ACADA and JCAD

	FY01		FY02	FY03
Systems	Target	Actual	Target	Target
M22 ACADA	6,721 [19,486 of 34,499 procured]	9,039 [21,765 of 34,499 procured]	0	0
Joint Chemical Agent Detector (JCAD)	0 [0 of 216,126 procured]	0 [0 of 216,126 procured]	0	0832

2.6.4.2 Current R&D Targets – JCAD

FY 2001 Targets	Actual Performance
- Complete EMD program planning and execution of project management functions. Prepare for and develop MS III program documentation and coordinate program with Joint Service IPT representatives - Complete hardware and software test units development - Complete development efforts of the prototype detectors - Complete developmental, preliminary qualification tests and field tests; initiate operational test and evaluation	None of the targets met. FY 2001 accomplishments: - Continued hardware and software development of breadboard prototypes units at an average unit cost of $44,667 - Continued systems EMD for prototype units, and logistics planning - Continued systems integration of systems components - Inititiated contractor engineering test and evaluation of breadboard prototype units.

2.6.4.3 Future R&D Targets – JCAD

FY 2002 Targets	FY 2003 Targets
- Complete hardware and software for production representative units delivery and reports - Complete systems engineering, manufacturing, and logistics development for final production representative units - Complete system integration on final MS III representative units - Complete Phase II engineering test and evaluation, production qualification tests, and operational tests	- Develop hardware and software updates based upon contractor and government developmental testing - Continue JCAD systems engineering and logistics planning - Continue system integration supporting government developmental tests - Continue government developmental test and evaluation and continued government operational test planning and preparation

2.7 CORPORATE GOAL 4: PROVIDE REAL-TIME HAZARD INFORMATION TO INFLUENCE CURRENT OPERATIONS *(NBC BATTLE MANAGEMENT)*

2.7.1 *Performance Goal 4.1* – Enable rapid communication of NBC hazards and data related to NBC defense (specialized forces, operational and logistics planning information) throughout the theater without burdening personnel or resources.

Current Materiel Solutions	Future Materiel Solutions
Joint Warning and Reporting Network (JWARN) Block I (Interim Standardization)	JWARN Block II JWARN Block III Joint Effects Model (JEM)

2.7.2 Materiel Solutions Performance Measurements

2.7.2.1 Current Procurement Targets – JWARN Block I

	FY01		FY02	FY03
Systems	Target	Actual	Target	Target
Joint Warning and Reporting Network (JWARN) Block I	516 [644 of 2,842 procured]	516 [644 of 2,842 procured]	0	Replaced by Block II

2.7.2.2 Current R&D Targets – JWARN – Block II and III

FY 2001 Targets	Actual Performance
- Continue Block II integration of NBC legacy and future detector systems - Develop NBC warning and reporting modules and battlespace management modules for use by Joint Services C4I systems - Start DT/OT of Block II C4I software modules and interfaces for legacy and future detector systems	None of the targets met. FY 2001 accomplishments: - Prepared documentation for start of System Development and Demonstration effort - Finalized Block II Software Development Plan Justification: - MS B not completed: Funds awaiting reprogramming

2.7.2.3 Future R&D Targets – JWARN – Block II and III

FY 2002 Targets	FY 2003 Targets
- Continue Block II integration of NBC legacy and future detector systems - Develop NBC warning and reporting modules and battlespace management modules for use by Joint Services C4I systems - Conduct Blok II modeling and simulation - Conduct Block II system T&E - Prepare integrated logistics support technical data	- Continue Block II integration of NBC legacy and future detector systems and conduct DT-I/ Operational Assessment for full system requirements - Start to prepare MS C documentation for Block II

2.7.2.4 Current R&D Targets – Joint Effects Model (JEM) Block I

FY 2001 Targets	Actual Performance
- *FY 2003 New Start*	- *FY 2003 New Start*

2.7.2.5 Future R&D Targets – Joint Effects Model (JEM) Block I and II

FY 2002 Targets	FY 2003 Targets
- *FY 2003 New Start*	- Complete transition from the technology base. Integrate counterforce, passive defense, and hazard/incident software models into a complete system. Develop logistics documentation, initiate Post Deployment Software Support Planning, and establish online document library and information network for data, research, and other program information - Update MS B program documentation and conduct MS B decision - Conduct source selection for development of a standardized hazard prediction model - Develop TEMP and Verification, Validation, and Accreditation Plan. Complete analysis of existing field test data associated with the hazard prediction models VLSTRACK, HPAC, and D2PC and identify data gaps - Prepare for and conduct Early Operational Assessment - Initiate Independent Validation and Verification effort. Develop and refine warfighter use cases - Perform engineering analysis and evaluation of software design documentation. Establish and conduct Chance Control Board - Award contract for development of engineering builds (software only) in support of the Block I effort

2.8 CORPORATE GOAL 5: ENHANCE PERSONNEL AND EQUIPMENT SURVIVABILITY – (*INDIVIDUAL DETECTION/PROTECTION/DECON*)

2.8.1 *Performance Goal 5.1* – Provide general warfighters with individual protective ensembles that protect against all NBC hazards.

Current Materiel Solutions	Future Materiel Solutions
Battledress Overgarment (Legacy System) Saratoga, JS Lightweight Integrated Suit Technology (JSLIST) Black Vinyl Overboots (Service O&M responsibility) 7, 14, 25-mil Gloves (Service O&M responsibility)	JSLIST Block I and II Glove Upgrades

2.8.2 Materiel Solutions Performance Measurements

2.8.2.1 Current Procurement Targets – JSLIST

Systems	FY01		FY02	FY03
	Target	Actual	Target	Target
JS Lightweight Integrated Suit Technology (JSLIST)	330,871 [1,207,315 of 4,728,784 procured]	371,851 [1,248,295 of 4,728,784 procured]	361,024	331,350

2.8.2.2 Current R&D Targets – JSLIST Block I Glove Upgrade

FY 2001 Targets	Actual Performance
- JSLIST Glove Block I MSIII	None of the targets met. FY 2001 accomplishments: - Started Operational Test and documentation transition to Block II glove program

2.8.2.3 Future R&D Targets – JSLIST Block II Glove Upgrade

FY 2002 Targets	FY 2003 Targets
- Initiate engineering and design of an integrated JSLIST Block II glove for DT/OT to meet air/ground usage requirements in a CB environment - Prepare program documentation for MS C	- Award multiple competitive contracts for system development and demonstration - Conduct durability and chemical validation testing for ground and aviation missions - Conduct project management and plan test readiness reviews - Conduct air/ground Operation Test and complete MS C

2.8.3 *Performance Goal 5.2* – Provide general warfighters with individual protective masks that protect against all NBC hazards.

Current Materiel Solutions	Future Materiel Solutions
M40/M40A1 Mask M42 Tank Mask (Legacy) MCU-2A/P Mask (Legacy)	Joint Service General Purpose Mask (JSGPM)

2.8.4 Materiel Solutions Performance Measurements

2.8.4.1 Current Procurement Targets – M40/M40A1 and Second Skin, Mask MCU-2/P

	FY01		FY02	FY03
Systems	**Target**	**Actual**	**Target**	**Target**
M40/M40A1 Mask	0 [1,341,087 of 786,906 procured]	0 [1,341,087 of 786,906 procured]	*n/a*	*Replaced by JSGPM*
Second Skin, Mask MCU-2/P	0 [0 of 615,856 procured]	150 [371,851 of 615,856 procured]	99,220	765,350

2.8.4.2 Current R&D Targets – JSGPM

FY 2001 Targets	Actual Performance
- Continue Joint Program Management/Systems Engineering and development of engineering change orders - Continue Joint Program/Project Management - Continue preparation of Program/Project documentation - Continue development contract for mask design and fabrication of prototypes and award EMD option - Continue Developmental T&E - Continue sustainment study for logistics support	All targets met. Additional FY 2001 accomplishments: - Continued preparation for Interim Progress Review and transition to the System Demonstration acquisition phase. These activities include finalization of the Acquisition Strategy, Test and Evaluation Master Plan, and the Manpower and Personnel Integration Plan - Continued Program Definition and Risk Reduction contract for mask design and 800 prototypes ($1,500 each) - Contractor initiated design of mask to Joint Service performance specifications with Joint Service input - Conduct Engineering Design Test planning. Testing ensures meeting Joint Service requirements for protection, communication, drinking, breathing resistance, and weight/bulk limitations - Continue sustainment study for logistics support - Initiated testing and evaluation of two, commercially available, escape masks

2.8.4.3 Future R&D Targets – JSGPM

FY 2002 Targets	FY 2003 Targets
- Conduct EMD, which includes system support packages for PQT/IOT&E. The contract includes delivery of 5,000 prototypes ($500 each) in 1QFY04 - Prepare program/project documentation to achieve MS C decision. Documentation includes: Acquisition Strategy, the Manpower and Personnel Integration Plan, and performance specifications - Execute logistics support plan - Initiate documentation and planning for DT/OT - Test redesigned prototype to assess shortcomings exposed during PDRR phase	- Continue preparation of program/project documentation to achieve MS C - Continue execution of logistics support plan. Develop manuals and finalization of supportability plans - Continue System Demonstration including system support packages for PQT/IOT&E - Continue documentation and planning for DT/OT - Continue development of a JSGPM variant as a lightweight complement to the JSGPM against limited threats

2.8.5 *Performance Goal 5.3* – Provide individual chemical detection equipment that allows manual identification of immediate CW hazards.

Current Materiel Solutions	Future Materiel Solutions
M8 paper (Service O&M responsibility) M9 paper (Service O&M responsibility) M256A1 Detector Kit (Service O&M responsibility)	Joint Chemical Agent Detector (JCAD)

2.8.6 Materiel Solutions Performance Measurements: JCAD (see 2.6.4.1)

2.8.7 *Performance Goal 5.4* – Provide aviators with individual protective ensembles that protect against all NBC hazards.

Current Materiel Solutions	Future Materiel Solutions
Aircrew Uniform Integrated Battledress (AUIB) (Legacy system) Chemical Protective Undercoverall (Service O&M responsibility) CWU-66/77 Aircrew Ensemble (Legacy system)	Joint Protective Aviator Ensemble (JPACE)

2.8.8 Materiel Solutions Performance Measurements

2.8.8.1 Current R&D Targets – JPACE

FY 2001 Targets	Actual Performance
- Complete initial prototype development and fabrication for DT - Developmental testing: Conduct simulant, human factor, compatibility, environmental, and live agent testing of initial prototypes. Various sizes of prototypes will be tested - Manufacture 100 improved prototypes for OT	Targets for JPACE met with the following exceptions: - Developmental testing: Conduct simulant, human factor, compatibility, environmental, and live agent testing of initial prototypes. Various sizes of prototypes will be tested

2.8.8.2 Future R&D Targets – JPACE

FY 2002 Targets	FY 2003 Targets
- Complete DT IIA material swatch testing and downselect best six candidate materials. Initiate DT IIB testing on the six candidates to verify system level performance requirements have been met - Fabricate 75 prototype ensembles of each of the six selected candidates for use in DT IIB - Complete development of patterns for use in fabrication of JPACE. Continue developing and updating program, logistics, and technical documentation required to support the development of JPACE	- Complete DT IIB testing and downselect to two candidates. Fabricate 350 prototype ensembles of each candidate for combined DT/OT. Initiate combined DT/OT system level testing and initial Operation Assessment to verify system level performance and assess operational suitability and durability. Testing includes aircraft integration testing on six aircraft and system level chemical simulant testing - Continue developing and updating program, logistics, and technical documentation required to ensure that JPACE will be fully supported when fielded - Initiate finalization of suite/fabric patterns

2.8.9 *Performance Goal 5.5* – Provide aviators (fixed-wing and rotary wing) with individual protective masks that protect against all NBC hazards.

Current Materiel Solutions	Future Materiel Solutions
Aircrew Eye/Respiratory Protective Mask (AERP)- Legacy System CB Respiratory System M45 Aviation Protective Mask M48 Apache Mask (Legacy System)	Joint Service Aviation Mask (JSAM)

2.8.10 Materiel Solutions Performance Measurements

2.8.10.1 Current Procurement Targets – CB Respiratory System, M45 and M48 Mask

	FY01		FY02	FY03
Systems	**Target**	**Actual**	**Target**	**Target**
CB Respiratory System	692 [5,035 of 7,919 procured]	484 [4,743 of 7,919 procured]	666	300
M45 Aviation Protective Mask	125 [39,013 of 35,613 procured]	0 [39,013 of 35,613 procured]	0	0
M48 Protective Mask	0 [0 of 3,877 procured]	1,609 [0 of 3,877 procured]	0	0

2.8.10.2 Current R&D Targets – Joint Service Aviation Mask (JSAM) and M48 Mask

FY 2001 Targets	Actual Performance
JSAM - Test planning working group activities including responsible test organization support and preparation for prototype evaluation - Perform program planning and execution of project management functions. Prepare for and develop program documentation and coordinate program with Joint Service IPT representatives - Continue two contractor prototype development, data delivery, and contractor development test. Begin prototype fabrication of approximately 20 masks - Contractor Program Management/Systems Engineering and development of engineering change orders	- All targets met
M48 - Complete Apache helicopter bracket design and limited fabrication for test. - Conduct verification flight testing to support air worthiness release. - Obtain Air Worthiness Release. - Complete New Material Release documentation.	- All targets met

2.8.10.3 Future R&D Targets – Joint Service Aviation Mask (JSAM) and M48 Mask

FY 2002 Targets	FY 2003 Targets
JSAM - Finalize PDRR test plans/procedures and evaluate PDRR prototypes. The Government will evaluate the prototypes for chemical agent permeation, fit factor, positive pressure breathing at altitude, anti-G	JSAM - Finalize system design and complete development. Begin logistics activities and sustainment planning to include tech order preparation, provisioning, and fielding plan

FY 2002 Targets	FY 2003 Targets
endurance, air crew life support equipment integration and aircraft interface checks, human factors and environmental factors - Complete initial development and qualification testing of prototypes. Deliver prototypes to the government for PDRR testing - Continue system engineering. Support government PDRR prototype testing and prepare for/conduct MS II and transition to engineering manufacturing development	- Continue program management activities and government management activities and government test planning in preparation for DT and OT - Complete system validation, develop production processes, and hard tooling to fabricate DT and OT units - Initiate materiel buy and begin assembly of 466 DT units at an average unit cost of $5,175
M48 - Award production contracts for bracket and hose assemblies. - Complete M48 system by marrying bracket/hose assemblies to existing M48 parts. - Field M48 systems.	- *n/a* (transitioned to production)

2.8.11 *Performance Goal 5.6* – Provide units with inherent capability to test and adjust protective mask fits for its warfighters.

Current Materiel Solutions	Future Materiel Solutions
M41 Protective Assessment Test System (PATS)	JS Mask Leakage Tester (JSMLT)

2.8.12 Materiel Solutions Performance Measurements

2.8.12.1 Current Procurement Targets – M41 PATS and JSMLT

Systems	FY01		FY02	FY03
	Target	Actual	Target	Target
M41 PATS	0 [7,224 of 5,440 procured]	0 [7,224 of 5,440 procured]	*Replaced by JS Mask Leakage Tester*	*n/a*
Joint Service Mask Leakage Tester	*n/a* [0 of 1,439 procured]	*n/a* [0 of 1,439 procured]	*n/a*	1,265

2.8.13 *Performance Goal 5.7* Provide warfighters with lightweight protective masks and ensembles for short-term exposure to NBC agents

Current Materiel Solutions	Future Materiel Solutions
None (interim measure-use of M40 series/MCU-2/P) None (interim measure-use of JSLIST)	JS Chemical Environment Survivability Mask (JCESM) JS Chemical Environment Survivability Suit (CESS)

2.8.14 Materiel Solutions Performance Measurements

2.8.14.1 Current R&D Targets – JCESM and CESS

FY 2001 Targets	Actual Performance
- *FY 2002 New start*	- *FY 2002 New start*

2.8.14.2 Future R&D Targets – CESM and CESS

FY 2002 Targets	FY 2003 Targets
- JCESM - Initiate Full System Development of Objective System. - Initiate CESS program- down select candidate suit technology - CESS- conduct limited technical tests and operational evaluation - CESS- conduct MS III	- JCESM- initial full system development of objective system - CESS- initiate procurement for SOCOM

2.8.15 *Performance Goal 5.8* Provide individuals with immediate decontamination capability to reduce life-threatening NBC hazard risk.

Current Materiel Solutions	Future Materiel Solutions
M291 skin decon kit (Purchase is a Service O&M responsibility) M295 individual equipment decon kit (Purchase is a Service O&M responsibility)	M291 skin decon kit (Sorbent based) M295 individual equipment Decon kit (Sorbent based)

2.8.16 Materiel Solutions Performance Measurements

2.8.16.1 Current R&D Targets – M291 and M295 Decon Kits

FY 2001 Targets	Actual Performance
<u>M291 Skin Decon Kit (Sorbent)</u> - Develop end item design using carbon cloth technology to facilitate absorption of the contaminant from the skin - Produce prototype hardware of the M291 skin decon kits with sorbent - Conduct toxicity testing of sorbent for skin decon - Develop engineering change proposal to incorporate sorbent into the M291 skin decon kit <u>M295 Equipment Decon Kit (Sorbent)</u> - Develop engineering change proposal for the M295 individual decon kits	Targets for M291 met with the following exceptions: - Develop engineering change proposal to incorporate sorbent into the M291 skin decon kit All M295 targets met.

2.8.16.2 Future R&D Targets – M291 and M295 Decon Kits (Sorbent based)

FY 2002 Targets	FY 2003 Targets
- Apply for FDA approval of M 291 skin decon kit	- None

2.8.17 *Performance Goal 5.9* Provide individuals and medics with medical pretreatments for exposure to CW agents.

Current Materiel Solutions	Future Materiel Solutions
Nerve Agent Pyridostigmine Pretreatment (NAPP) (Service O&M responsibility)	Topical Skin Protectant (TSP) Improved NAPP Active Topical Skin Protectant (aTSP) CW Agent Prophylaxis Cyanide Pretreatment

2.8.18 Materiel Solutions Performance Measurements

2.8.18.1 Current R&D Targets – Improved NAPP and TSP

FY 2001 Targets	Actual Performance
NAPP - Complete validation studies and submit licensure documentation for NAPP TSP - Prepare sample packaging and validate manufacturing procedure	NAPP Targets not met. FY 2001 accomplishments: - Initiate surrogate validation, 2-year clinical bioequivalence study, and 2-year studies to define pharmacology of NAPP. TSP - All targets met.

2.8.18.2 Future R&D Targets – Improved NAPP and TSP

FY 2002 Targets	FY 2003 Targets
NAPP - Continue storage and stability testing - Conduct FDA required additional studies TSP - Prepare sample packaging and validate manufacturing procedures for TSP	NAPP - Complete storage and stability testing and complete FDA required additional studies TSP - Complete FDA manufacturing requirements

2.8.18.3 Current R&D Targets – Active Topical Skin Protectant and CW Agent Prophylaxis

FY 2001 Targets	Actual Performance
- Initiate Phase 0 studies for efficacy and safety of best candidate reactive moieties for aTSP - Initiate Phase 0 studies for efficacy and safety of lead CW Agent Prophylaxis - Select lead candidate CW Agent Prophylaxis for *in vivo* and *in vitro* screens	- All targets met - Both identified as *Defense Technology Objectives(DTOs)*

2.8.18.4 Future R&D Targets – Active Topical Skin Protectant and CW Agent Prophylaxis

FY 2002 Targets	FY 2003 Targets
- *See DTO descriptions at appendix 1 of this report*	- *See DTO descriptions at appendix 1 of this report*

2.8.19 *Performance Goal 5.10* Provide individuals and medics with medical post treatments for CW agents.

Current Materiel Solutions	Future Materiel Solutions
Nerve Agent Antidote Kit (NAAK) (Service O&M responsibility) Convulsant Antidote Nerve Agent (CANA) (Service O&M responsibility) Sodium thiosulfate/nitrate (Service O&M responsibility)	Multi-chamber Autoinjector Improved CANA Vesicant Agent Countermeasures Advanced Anticonvulsant

2.8.20 Materiel Solutions Performance Measurements

2.8.20.1 Current R&D Targets – Multi-Chamber Autoinjector and Advanced Anticonvulsant

FY 2001 Targets	Actual Performance
Multi-chamber Autoinjector - Submit support documentation for FDA licensure - Conduct MS III in-process review	- All targets met
Advanced Anticonvulsant - Initiate Phase I safety study - Initiate multi-year toxicology studies - Initiate validation of animal efficacy model	All targets met and completed - Production of current Good Manufacturing Practice (cGMP) pilot lots for preclinical studies for Advanced Anticonvulsant - Initiation of a 2-year preclinical efficacy study in nonhuman primates for Advanced Anticonvulsant

2.8.20.2 Future R&D Targets – Multi-Chamber Autoinjector and Advanced Anticonvulsant

FY 2002 Targets	FY 2003 Targets
Multi-chamber Autoinjector - Conduct FDA required additional studies for licensure	Multi-chamber Autoinjector - Complete FDA required additional studies for licensure
Advanced Anticonvulsant - Complete multi-year toxicology studies - Complete 2-year pre-clinical efficacy study in non-human primates - Formulate advanced anticonvulsant in autoinjector for planned clinical studies	Advanced Anticonvulsant - Prepare and submit documentation for Investigational New Drug application - Continue development of the manufacturing processes, material requirements, formulation, and packaging to be used in clinical studies - Prepare documentation for a conduct MSII in-process review - Complete evaluation of FDA approved seizure drugs for nerve agent induced seizures

2.8.21 *Performance Goal 5.11* Provide individuals and medics with pre-treatments for BW agents.

Current Materiel Solutions	Future Materiel Solutions
Anthrax vaccine Smallpox vaccine	Biological Defense Vaccines, *e.g.*, Multivalent Equine Encephalitis, Plague, Ricin and Next Generation Anthrax vaccine

2.8.22 Materiel Solutions Performance Measurements

2.8.22.1 Current R&D Targets – Biological Defense Vaccines

FY 2001 Targets	Actual Performance
- Continue Phase I effort for Smallpox vaccine - Initiate Phase II effort for Smallpox vaccine	All targets met. Additional accomplishments: - Submitted IND application and executed clinical trial for Vaccinia Immune Globulin (VIG). - Initiated assay development for Smallpox vaccine. - Conducted clinical trial for smallpox vaccine licensure studies. - Began manufacture of consistency lots and revalidation of Plaque Reduction Neutralization assay for VIG
- Continue Phase I effort for Tularemia vaccine	Target not met. FY 2001 accomplishments: - Continued manufacturing process development for Tularemia vaccine including formulation studies. - Conducted development and validation of assays for virulence and potency - Began development of efficacy testing method in animals
- Continue Phase I effort for Recombinant Botulinum vaccine	Target not met. FY 2001 accomplishments: - Continued manufacturing process development and purification refinement of Botulinum vaccines - Prepared master and working seed banks - Began preparation for manufacture of cGMP pilot lots
- Initiate Phase I for Next Generation Anthrax Vaccine (NGAV)	Target not met. FY 2001 accomplishments: - Initiated technology transfer and process definition for a candidate recombinant protective antigen NGAV
- Initiate Phase I for Multivalent Equine Encephalitis (MEE)	Target not met. FY 2001 accomplishments: - Completed pilot lot manufacturing in progress. - Conducted stability and formulation studies and performed assay development and validation for VEE 1A vaccine
- Continue Phase I for Plague	Target not met. FY 2001 accomplishments: - Continued component advanced development for a manufacturing process for combined F1+V Plague vaccine candidate.
- For Brucella, Plague, VEE vaccines, Staphylococcal Enterotoxin B, see section 3.0: S&T Performance Goals & Measures	- *n/a*

2.8.22.2 Future R&D Targets – Biological Defense Vaccines

FY 2002 Targets	FY 2003 Targets
- Tularemia Vaccine: Continue efficacy testing and begin immunogenicity studies for Tularemia vaccine - Begin pilot lot manufacturing and stability testing	- Complete characterization studies and surrogate marker of efficacy assay - Begin Phase I clinical trial execution and monitoring - Complete bulk stability and final container stability testing of pilot lot - Submit IND application to FDA
- Continue manufacturing process refinement of serotypes for the Recombinant Botulinum Vaccine including antigen characterization and assay development and validation - Begin pilot lot production of second serotype and conduct non-clinical testing for multivalent Recombinant Botulinum vaccine - Complete serologies and data analysis of the Pentavalent Botulinum Toxoid booster study and prepare final report for submission to the FDA	- Continue manufacturing process development and begin process validation - Begin bulk stability and final container stability testing of pilot lot - Begin single serotype phase 1 clinical trial preparation
- Equine Encephalitis Vaccines: Complete process development initiate safety studies for VEE 1A component of the vaccine - Manufacture cGMP pilot lots for other Multivalent Encephalitis components	- Continue assay development and validation - Continue process optimization including demonstration runs - Begin process validation and pilot lot manufacturing for VEE 1E component - Begin efficacy testing and continue bulk stability testing - Begin container stability testing - Conduct higher animal species testing and equine safety study
- Plague Vaccine: Continue process development and initiate comparability studies in non-human primates for Plague vaccine - Initiate assay development and validation	- Manufacture and characterize master seed and working seed banks - Continue assay development and validation - Complete process development work and conduct pilot lot manufacturing - Begin process toxicity testing and immunogenicity studies - Begin bulk stability, container stability, and reconstitution stability testing - Conduct pre-IND preparation
- Next Generation Anthrax Vaccine: Continue process definition studies of NGAV including stability and formulation studies	- Complete process definition work for a candidate recombinant protective antigen NGAV - Manufacture and characterize master seed and working seed banks - Conduct assay development and validation

FY 2002 Targets	FY 2003 Targets
- Smallpox Vaccine: Continue consistency lot manufacture and conduct stability testing for Smallpox vaccine - Initiate Phase 2b clinical trial for Smallpox vaccine - Develop manufacturing capability for VIG and initiate BLA process	- Complete reproductive toxicology studies for Smallpox vaccine - Continue Smallpox and Vaccinia Immune Globulin (VIG) stability studies - Initiate 2nd and 3rd parts of a three-part Phase 2b large-scale clinical trial (safety and immunogenicity study for > 3000 subjects) for Smallpox vaccine to satisfy FDA requirement for licensure - Achieve baseline stockpile quantities and begin warm base lot manufacturing (assuring a continuous manufacturing capability) for both Smallpox vaccine and VIG - Begin BLA preparation and compilation. Continue IND annual reports and manufacturing amendments for Smallpox vaccine and VIG

2.8.23 *Performance Goal 5.12* Provide individuals and medics with post-treatments for BW agents.

Current Materiel Solutions	Future Materiel Solutions
Antibiotics (Service O&M responsibility)	Broad spectrum antibiotics Antitoxins Anti-viral drugs

2.8.24 Materiel Solutions Performance Measurements

2.8.24.1 Current R&D Targets

FY 2001Targets	Actual Performance
- Technology base efforts	- Technology base efforts Described in Section 3.0 (Projects TB2 and TB3)

2.8.24.2 Future R&D Targets

FY 2002 Targets	FY 2003 Targets
- Technology base efforts	- Technology base efforts

2.9 CORPORATE GOAL 6: MAINTAIN GROUND, AIR AND MARITIME OPERATIONAL TEMPO *(OPERATIONAL DECON/COLLECTIVE PROTECTION)*

2.9.1 *Performance Goal 6.1* Provide crewmembers with a limited capability to reduce the level of contamination on vehicles and weapon systems.

Current Materiel Solutions	Future Materiel Solutions
M11 Decon App, Portable (Legacy system) M13 Decon App, Portable (Legacy system) (both with DS-2)	M100 Sorbent Decon System (SDS)

2.9.2 Materiel Solutions Performance Measurements

2.9.2.1 Current Procurement Targets – XM100 Sorbent Decon System

	FY01		FY02	FY03
Systems	**Target**	**Actual**	**Target**	**Target**
M100 Sorbent Decon System	40,000 [40,000 of 1,120,544]	30,000 [30,000 of 1,120,544]	120,000	120,000

2.9.3 *Performance Goal 6.2* Provide an operational capability to reduce the level of contamination on vehicles and weapon systems.

Current Materiel Solutions	Future Materiel Solutions
M17A2 Lightweight Decon System (Legacy System)	M21 Decontaminant Pumper M22 High Pressure Washer, components of the Modular Decon System (MDS)

2.9.4 Materiel Solutions Performance Measurements

2.9.4.1 Current Procurement Targets – MDS and JSFXD

	FY01		FY02	FY03
Systems	**Target**	**Actual**	**Target**	**Target**
Modular Decontamination System	130 [130 of 465]	0 [0 of 465]	27	114
Joint Service Fixed Site Decon	0 [0 of 1,932]	0 [0 of 1,932]	54,424	116,545

2.9.5 *Performance Goal 6.3* Ensure vehicles, vans and ships have a protected environment that keeps NBC hazards out.

Current Materiel Solutions	Future Materiel Solutions
Various Gas-Particulate Filter Unit (GPFU) configurations (Legacy systems) Modular Collective Protection Equip. (Legacy systems) Selected Area CPS, Ship CPE, (Legacy systems) Ship CPS Backfit	Joint CP Equipment (JCPE) Shipboard Collective Protection Equipment (SCPE)

2.9.6 Materiel Solutions Performance Measurements

2.9.6.1 Current Procurement Targets – Ship CPS Backfit

	FY01		FY02	FY03
Systems	**Target**	**Actual**	**Target**	**Target**
Ship CPS Backfit (protective zones backfitted)	5 [13 of 51 procured]	6 [13 of 51 procured]	5	7

2.9.6.2 Current R&D Targets – Joint Collective Protection (CP) Equipment

FY 2001 Targets	Actual Performance
- Perform program planning and project management - Prepare for and develop program documentation and coordinate program with	- All targets met. <u>In addition</u>: - Initiated development of a pleatable charcoal/HEPA bonded filter to replace two CB filters used in collective protection systems to reduce installation time, logistics,

FY 2001 Targets	Actual Performance
Joint Service IPT - Begin development of improved carbon filters to extend service life and reduce production costs - Complete development of and test improved 200 CFM and FIF filters - Begin development and test of improved motorblowers to improve efficiency, reliability, size and weight - Continue development and testing of lightweight ECU for transportable collective protection systems	and cost - Prepared technical drawings for Integrated Logistics Support (ILS) for the Bump Through Door (BTD) airlock modification to the transportable collective protection systems and medical systems - Performed development and testing of a prototype one-piece 32-foot liner, 8-foot extension and vestibules for use in the Small Shelter System to provide the Air Force EMEDS system with collective protection capability until JTCOPS is fielded. - Completed market surveys and evaluated systems capable of meeting the Operational Requirements Document (ORD) for a Chemically/biologically Hardened Air Transportable Hospital (CHATH) transportable latrine system for use with EMEDS.

2.9.6.3 Future R&D Targets – Joint Collective Protection (CP) Equipment

FY 2002 Targets	FY 2003 Targets
- Initiate development and testing of two types of improved COTS LP HEPA filters to extend filter life and improve performance - Test ten improved M48A1 and M56 carbon filter with live agents to complete qualification of filter design - Complete development of a single pleatable charcoal/HEPA bonded filter to replace two CB filters used in collective protection systems to reduce installation time, logistics, and cost - Conduct testing of RFU acceptance tester. RFU is designed to eliminate low level contamination brought into collective protection systems by personnel or equipment - Increase efficiency of CPS supply fans by developing a variable speed air supply system to allow the CPS system to operate at peak performance over the entire range of filter loading - Complete development and testing of FFA 400-100 and M93 candidate motorblowers for CB shelter systems to improve efficiency, reliability, size, and weight. - Complete development of the universal NBC ECU adapter that can apply a transportable cooling coil to the FFA 580 blower and other FFA blower configurations. - Initiate development of a new Air Force shelter configuration which combines a medium size shelter between two small shelters using a M28 collective protection liner.	- Complete development of 2000 CFM particulate filters to reduce logistics costs - Initiate development of a modified impingement filter for ships to reduce cost of filter maintenance and logistics - Complete live agent testing of improved 100/200 CFM gas filters - Complete development and testing of ten improved 100/200 CFM gas filters to provide TIC protection - Perform development and testing to increase efficiency of CPS supply fan motors to operate at peak performance over the entire range of filter loading - Initiate development and testing of an integrated collective protection (CP) power transfer kit for Transportable Collective Protection System (TCPS). Complete development of a modified M28 liner for large capacity shelters

2.9.6.4 Current R&D Targets – Shipboard Collective Protection (SCPE)

FY 2001 Targets	Actual Performance
- Continue testing of CPS fan rotors on designated ships - Continue long-term testing of shipboard filter improvements - Prepare and update documentation (test reports, Tech Manuals and TDP)	All targets met. In addition: - Completed testing of 9 V-Cell (mini-pleat) Limited Protection (LP) HEPA filters. - Initiated shock and vibration testing on four COTS LP HEPA filters. - Transitioned COTS LP HEPA filter to JCPE for further development. - Performed literature search and developed a table listing performance of shipboard CPS HEPA filters versus high threat toxic industrial chemicals (TIC) and toxic industrial materials (TIM) - Initiated development and testing of two electronic differential pressure gauges for remote reading to reduce shipboard maintenance

2.9.6.5 Future R&D Targets – Shipboard Collective Protection (SCPE)

FY 2002 Targets	FY 2003 Targets
- Continue shipboard testing of improved CPS fan. Shipboard testing is required to verify actual noise reduction in a fan room and adjacent manned spaces on board a ship. Use test data to revise CPS fan rotor performance specification. Improved CPS fan rotors will increase efficiency and reduce noise levels by 12 to 17 decibels - Complete third year of verification testing to validate the four-year performance of improved prefilters and HEPA filters - Continue evaluation of HEPA filter performance degradation after TIC/TIM exposure - Continue development and testing of two electronic differential pressure gauges for remote reading to reduce shipboard maintenance - Prepare and update documentation (test reports, Tech Manuals and TDP). Initiate transition of selected efforts to JCPE	- Complete shipboard testing of improved CPS fan rotors. Test data will be used to revise CPS fan rotor performance specification - Complete final year of verification testing to validate the four-year performance of improved prefilters and HEPA filters - Complete testing and evaluation of HEPA filter performance degradation after TIC/TIM exposure - Complete development and testing of two electronic differential pressure gauges for remote reading to reduce shipboard maintenance

2.9.7 *Performance Goal 6.4* Provide a hazard-free environment for mobile command and control operations.

Current Materiel Solutions	Future Materiel Solutions
M20A1 SCPE (Legacy system) Portable CPS (Legacy system)	Joint Transportable Collective Protection Shelter (JTCOPS) Block I Joint CP Equipment

2.9.8 Materiel Solutions Performance Measurements

2.9.8.1 Current R&D Targets – Joint Transportable Collective Protection Shelter Block I

FY 2001 Targets	Actual Performance
- Conduct program management functions, obtain engineering support, prepare documentation, and fund participation of Joint Service IPT - Complete the fabrication of one prototype from each contract for EDT	Targets met with the following exception: - Complete the fabrication of one prototype from each contract for EDT Justification: - Revised the acquisition strategy to a block approach to align with user priorities. Revised the MS B documentation and the development contract RFP for Block I.

2.9.8.2 Future R&D Targets – Joint Transportable Collective Protection Shelter Block I

FY 2002 Targets	FY 2003 Targets
- Award development contract for Block I - Conduct entire design phase of the contract and begin the prototype fabrication phase	- Conduct MS B Decision Review for Block I - Release a RFP, evaluate proposals, and award a contract for Block I - Begin the design phase of the contract

2.9.8.3 Current & Future R&D Targets: Joint CP Equipment (see 2.9.6.2 and 2.9.6.3)

2.10 CORPORATE GOAL 7: SUSTAIN OPERATIONS, RECOVERY AND RECONSTITUTION EFFORTS *(RESTORATION OPERATIONS)*

2.10.1 *Performance Goal 7.1* Provide units with a capability to eliminate all contamination on vehicles and weapon systems.

Current Materiel Solutions	Future Materiel Solutions
M12 Power-Driven Decon Apparatus (Legacy system)	M21 Decontaminant Pumper M22 High Pressure Washer, components of the Modular Decon System (MDS)

2.10.2 Materiel Solutions Performance Measurements

2.10.2.1 Current & Future Procurement Targets – M21/22 Modular Decon System (see 2.9.4)

2.10.3 *Performance Goal 7.2* Provide units with a capability to eliminate all contamination on terrain and fixed sites.

Current Materiel Solutions	Future Materiel Solutions
M12 Power-Driven Decon Apparatus (Legacy system)	Joint Service Fixed Site Decontamination System (JSFXD)- Blocks I, II, and III

2.10.4 Materiel Solutions Performance Measurements

2.10.4.1 Current R&D Targets – Joint Service Fixed Site Decontamination System (JSFXD)

FY 2001 Targets	Actual Performance
- Procure and test prototype decontaminants to meet the casualty decon requirements - Complete technical documentation - Prepare MSII documentation - Begin testing of casualty decontaminants to support FDA approval - Prepare documentation for MSI/II for Block I and Block III - Prepare Logistics Support Packages and complete MSIII documentation for Block I - Conduct DT/OT on decon applicators	Targets met with the following exceptions: - Preparation of solicitation and SDD contract slipped to FY 2002 for Block II - Start of Block I Development Test (DT)/Operational Test (OT) slipped to FY 2002 Additional FY 2001 Accomplishments: - Prepare solicitation package Block III - Initiated test methodology development and initial toxicology testing to support downselect and FDA approval of Block III/skin casualty decontaminants

2.10.4.2 Future R&D Targets – Joint Service Fixed Site Decontamination System (JSFXD)

FY 2002 Targets	FY 2003 Targets
- Continue toxicology testing and other evaluations necessary for FDA approval to support downselect of Block III skin/casualty decontaminants - Award PDRR contract(s) for Block II family of applicators system to develop prototype applicator and containment systems for evaluation (15 systems at average cost of $100K) - Perform Early Operational Assessment and initiate DT of Block II family of applicator systems - Complete DT/OT on family of decontaminants for Block I. Complete MS C documentation for Block I - Incorporate lessons learned from OT into logistics support documentation for Block I family of decontaminants - Prepare documentation and test reports, conduct downselect of medical/skin decontamination in support of Block III EMD contract award	- Initiate DT/OT of family of applicators for Block II using GFE and engineering models applicators - Initiate clinical testing for FDA approval for skin decontaminants Block III - Award and execute SDD contract for FDA approved medical skin decontaminants Block III

2.10.5 *Performance Goal 7.3* Provide units with a capability to eliminate all contamination on sensitive equipment and avionics.

Current Materiel Solutions	Future Materiel Solutions
None	Joint Service Sensitive Equipment Decon System (JSSEDS) Block I

2.10.6 Materiel Solutions Performance Measurements

2.10.6.1 Current R&D Targets – JSSEDS Block I

FY 2001 Targets	Actual Performance
- Block I MSI preparation and coordination with JSIG and JSMG - Block I Competitive Prototype Contract and Contracting Support - Initial evaluation of prototype	All targets met. In addition: - Completed performance specifications for RFP to support development contract for Block I

2.10.6.2 Current R&D Targets – JSSEDS Block I

FY 2002 Targets	FY 2003 Targets
- Award Block I Competitive Contract - Evaluate Block I prototypes during competitive "shoot-off" to determine decontamination efficacy	- Conduct Block I program Interim Progress Review (IPR) to finalize Block I technology and system design - Award contract to fabricate Block I developmental test systems which implement design improvements from the prior year competitive prototypes - Initiate pre-production Block I system test design

2.10.7 *Performance Goal 7.4* Provide units with a capability to eliminate all contamination on vehicle/aircraft interiors

Current Materiel Solutions	Future Materiel Solutions
None	Joint Service Sensitive Equipment Decon System (JSSEDS) - Blocks II and III

2.10.8 Materiel Solutions Performance Measurements

2.10.8.1 Current R&D Targets – JSSEDS Blocks II and III

FY 2001 Targets	Actual Performance
- Technology base efforts	- Technology base efforts Described in Section 3.0

2.10.8.2 Current R&D Targets – JSSEDS Blocks II and III

FY 2002 Targets	FY 2003 Targets
- Technology base efforts	- Prepare and submit Block II/III MS B documentation, which includes Test and Evaluation Master Plan, System Acquisition Master Plan, and Acquisition Program Baseline - Prepare RFP for Block II/III combined development effort

2.10.9 *Performance Goal 7.5* Monitor the presence/absence of CW agent contamination after decon.

Current Materiel Solutions	Future Materiel Solutions
Chemical Agent Monitor (CAM) (Legacy system) Improved CAM (ICAM)	Joint Chemical Agent Detector

2.10.10 Materiel Solutions Performance Measurements

2.10.10.1 Current Procurement Targets – ICAM

	FY01		FY02	FY03
Systems	Target	Actual	Target	Target
ICAM	3,003 [21,370 of 25,003 procured]	3,502 [22,812 of 25,003 procured]	0	0

2.10.10.2 Current & Future R&D Targets – JCAD (See section 2.6.4)

2.10.11 *Performance Goal 7.6* Monitor the presence/ absence of CW agent contamination in water.

Current Materiel Solutions	Future Materiel Solutions
M272A1 Water Test Kit (Service O&M responsibility)	Joint CB Agent Water Monitor (JCBAWM)

2.10.12 Materiel Solutions Performance Measurements

2.10.12.1 Current R&D Targets – Joint CB Agent Water Monitor (JCBAWM)

FY 2001 Targets	Actual Performance
- Technology base efforts	- Technology base efforts Described in Section 3.0

2.10.12.2 Future R&D Targets – Joint CB Agent Water Monitor (JCBAWM)

FY 2002 Targets	FY 2003 Targets
- Technology base efforts	- Technology base efforts

2.10.13 *Performance Goal 7.7* Provide a hazard-free environment for long-term command and control operations.

Current Materiel Solutions	Future Materiel Solutions
Fixed Site CPS (Legacy system)	Joint CP Equipment Joint Transportable CP Shelter (JTCOPS)

2.10.14 Materiel Solutions Performance Measurements

2.10.14.1 Current & Future R&D Targets – Joint Collective Protection (CP) Equipment (see 2.9.6)

2.10.14.2 Current & Future R&D Targets – Joint Transportable Collective Protection (CP) Shelter (JTCOPS) (see 2.9.8)

2.10.15 *Performance Goal 7.8* Provide a hazard-free environment for forward tactical medical operations.

Current Materiel Solutions	Future Materiel Solutions
M51 Shelter (Legacy system) CB Protective Shelter (CBPS)	Joint CP Equipment Joint Transportable Collective Protection System (JTCOPS) CBPS P3I

2.10.16 Materiel Solutions Performance Measurements

2.10.16.1 Current Procurement Targets – CBPS

	FY01		FY02	FY03
Systems	Target	Actual	Target	Target
CB Protective Shelter (CBPS)	26 [155 of 779 procured]	10 [138 of 779 procured]	32	27

2.10.16.2 Current and Future R&D Targets – Joint CP Equipment (see 2.9.6)

2.10.16.3 Current and Future R&D Targets – JTCOPS (see 2.9.8)

2.10.16.4 Current R&D Targets – CBPS P3I

FY 2001 Targets	Actual Performance
-*n/a* (FY02 start)	

2.10.16.4 Future R&D Targets – CBPS P3I

FY 2002 Targets	FY 2003 Targets
- Develop design concept for CBPS airborne and heavy versions - Coordinate with user and field representatives on requirements and logistics supportability - Award a three phase contract for design and fabrication of a self-powered Environmental Support System (ESS) - Award Phase I in FY 2002 to develop an ESS that will meet the requirements for CBPS-light, heavy, and airborne versions - Fabricate one prototype and conduct initial performance and reliability testing	- Fabricate two ESS prototypes at unit cost of $250,000 and finalize design and limited Technical Data Package - Conduct performance testing on one ESS prototype - Finalize design concepts for CBPS light, heavy, and airborne applications - Obtain and initiate modification of heavy and airborne platforms for integration

2.10.17 *Performance Goal 7.9* Provide a hazard-free environment for long-term rear-area medical operations.

Current Materiel Solutions	Future Materiel Solutions
CP DEPMEDS/CHATH	Joint Transportable Collective Protection System (JTCOPS)

2.10.18 Materiel Solutions Performance Measurements

2.10.18.1 Current Procurement Targets – CP DEPMEDS/CHATH

	FY01		FY02	FY03
Systems	Target	Actual	Target	Target
CP DEPMEDS/ CHATH	8 [8 of 14 procured]	8 [8 of 14 procured]	3	0

2.10.18.2 Current and Future R&D Targets – JTCOPS (see 2.9.8)

2.10.19 *Performance Goal 7.10* Develop medical identification and diagnosis device capable of identifying multiple BW agents in clinical and environmental sources.

Current Materiel Solutions	Future Materiel Solutions
None (interim measure- manual medical diagnoses and Theater Army Medical Labs)	Joint Biological Agent Identification and Diagnostic System (JBAIDS)

2.10.20 Materiel Solutions Performance Measurements

2.10.20.1 Current R&D Targets – JBAIDS

FY 2001 Targets	Actual Performance
- Technology base efforts	- Technology base efforts Described in Section 3.0

2.10.20.2 Current R&D Targets –JBAIDS

FY 2002 Targets	FY 2003 Targets
- Initiate design improvements of units transitioning from DTO and begin fabrication of EDT units - Conduct EDT - Initiate submission of Identification Assays to the FDA for regulatory approval - Initiate Integrated Logistics Support analysis development and technical drawings package requirements - Initiate development of technical manuals	- Continue design and production of six additional JBAIDS biological organism Identification Assays - Continue FDA regulatory process of system equipment - Complete requirements for FDA regulatory approval of ten assays - Complete Integrated Logistics Support analysis and technical drawings package requirements - Complete technical manual development - Initiate LRIP of thirty JBAIDS units - Perform PQT/IOT&E - Modify and fabricate test systems and hardware

CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM PERFORMANCE PLAN SCIENCE AND TECHNOLOGY BASE PERFORMANCE GOALS AND MEASURES

3.0 OVERVIEW

The science and technology base (S&T) of the Chemical and Biological Defense Program provides essential capabilities to develop technological advantage over any potential adversaries and prevent technological surprise. Within S&T there are three budget activities and three research areas, and project funding codes for each. (See Table 1.)[1]

Table 1. CBDP Science and Technology Base Project Funding Codes

	Research Area		
	Non-Medical S&T	Medical S&T	
Budget Activity (Program Element)	**CB Defense**	**Chemical Defense**	**Biological Defense**
BA1 - Basic Research (0601384BP)	CB1	TC1	TB1
BA2 - Applied Research (0602384BP)	CB2	TC2	TB2
BA3 - Advanced Technology Development (0603384BP)	CB3 and CP3	TC3	TB3

The approach for identifying and developing quantitative performance goals and measures on an annual basis is not always well suited for evaluating the progress of S&T efforts. The long term nature of many of these efforts makes the identification of quantitative measures on an annual basis meaningless (for example, how many breakthroughs in basic science were made last year.) However, using an approach similar to those used in the performance plans of other federal research centers—including the National Academies of Science, the National Institutes of Health, and the National Science Foundation—there are a variety of qualitative and quantitative performance measures that may be used to demonstrate progress of S&T efforts towards outcomes, which fulfills the requirements of the GPRA.

The basic performance measure established for S&T efforts is the independent expert panel review. The CBDP has adopted this practice using an independent panel of scientists from outside the Department to provide an assessment of the funding and research areas within the program. This process, known as the Technology Area Review and Assessment (TARA), has been conducted annually by the CBDP. The TARA panel provides a presentation of their findings and recommendations to the Defense Science and Technology Advisory Group, the senior leaders within the Department responsible for S&T within DoD.

3.1 CB DEFENSE S&T PLANNING

To ensure U.S. military preeminence in the long term, the Department must continue to focus investments on new generations of defense technologies. The Defense Science and Technology Strategy, with its supporting Basic Research Plan, Joint Warfighting Science and Technology Plan, and Defense Technology Area Plan, is the foundation of the science and technology (S&T) program. The Office of the Secretary of Defense, the Joint Staff, the military departments, and the defense agencies collaboratively develop the S&T program. Objectives of S&T planning are to:

- ensure projects support warfighter requirements,
- identify gaps in existing defense and commercial research,

[1] Biological Warfare Defense programs funded under DARPA project BW-01 are not addressed in this performance plan except for those projects identified as Defense Technology Objectives.

- ensure collaborative planning and execution of the S&T program,
- reduce undesired duplication of effort,
- provide the basis for independent expert panel reviews.

3.2 DOD CB DEFENSE SCIENCE AND TECHNOLOGY BASE PROGRAM

This section provides the objectives and metrics for the overall CB defense S&T program. An overall assessment is provided below. Actual and planned performance on specific projects is detailed in the following sections on S&T.

3.2.1 CB Defense Science and Technology Outcome Measure

CB Defense S&T is… …minimally effective when…	… successful when…
• All major commodity areas are rated GREEN and no sub-areas are rated RED by the TARA panel. • Research efforts contribute to increased knowledge regarding CB threats and science and technologies to defend against these threats. • Projects support goals and timelines stated in planning documents, specifically the *Joint Warfighting Science and Technology Plan* and the *Defense Technology Area Plan*.	• All commodity areas are rated GREEN by the TARA panel. • New capabilities are successfully demonstrated and transition to advanced development.

3.2.1.1 Metric Description. The metric for science and technology base projects is a qualitative assessment of the results of basic research, applied research, and advanced technology development compared to their intended purposes. This qualitative methodology for measuring the outcomes of the science and technology base is allowed by the GPRA (31 USC 1115(b)) as an alternative to the quantitative performance measures. The approach for identifying and developing quantitative performance goals and measures on an annual basis is not always well suited for evaluating the progress of research efforts. The long term nature of many of these efforts makes the identification of quantitative measures on an annual basis meaningless (for example, how many breakthroughs in basic science were made last year.) This approach is similar to those used in the performance plans other federal research centers—including the National Academies of Science, the National Institutes of Health, and the National Science Foundation. Qualitative performance measure are provided for each of the projects listed in table 1. Qualitative performance measures are assessed by an independent panel as well as by the accomplishment of specific project targets identified and detailed in each of the project areas below. The assessment includes an evaluation of the information provided to determine whether it is sufficient information to allow for an accurate, independent determination of the program activity's performance. An important element of the research efforts—especially for basic and applied research—is the evaluation and elimination of unsuccessful technologies. While not always identified as a specific target, the scientific method contributes to increased knowledge by eliminating efforts that will not contribute to project objectives.

3.2.1.2 Validation and Verification Methodology. The basic performance measure established for S&T efforts is the *independent expert panel review*.[2] This is in keeping with White House guidance to ensure that independent assessments of research programs evaluate

[2] *Evaluating Federal Research Programs: Research and the Government Performance and Results Act*, Washington, D.C: National Academy Press, 1999.

both the quality of programs and progress of research towards stated goals.[3] The CBDP has adopted this practice using an independent panel of scientists from outside the Department to provide an assessment of the funding and research areas within the program. This process, known as the Technology Area Review and Assessment (TARA), is conducted annually by the CBDP. The TARA panel provides a presentation of their findings and recommendations to Defense Science and Technology Advisory Group, the senior leaders within the Department responsible for S&T within DoD. Table 2 provides a summary of the assessment of each of the commodity areas within the CBDP, and table 3 provides the assessment by the TARA Panel of each of the DTOs presented during the FY2001 review.

Table 2. 2001 TARA Assessment of CB Defense S&T Commodity Areas

CB Defense Science and Technology Commodity Area	*TARA Rating*
DETECTION	GREEN
– Chemical Detection	GREEN
– Biological Detection	GREEN
– Modeling and Simulation	GREEN
PROTECTION	GREEN
– Non-Medical	GREEN
– Individual Protection	GREEN
– Collective Protection	GREEN
– Medical	GREEN
– Medical Chemical Defense	GREEN
– Medical Biological Defense	GREEN
DECONTAMINATION	GREEN

3.2.2 Assessment of CB Defense Science and Technology Outcome Measure

Overall, the DoD CBDP science and technology base has been effective. All areas have been rated green by the TARA panel. In addition, there were several technologies that completed successful demonstrations over the past year, and as detailed in the following sections, there are several examples of technology transitions to advanced development.

3.3 DEFENSE TECHNOLOGY OBJECTIVES

The Department's commitment to transforming U.S. military forces requires robust and stable funding for the S&T program. S&T expenditures support basic research as well as focused investments guided by defense technology objectives (DTOs). DTOs provide a framework for S&T efforts by identifying:

- What specific technologies will be developed and/or demonstrated.
- What specific milestones are to be reached, using what approaches.
- Which customers will benefit.
- What specific benefits the customers will gain.
- What level of funding will be programmed and from what sources.
- What quantitative metrics will indicate progress.

[3] See memorandum from The White House, Neal Lane and Jacob J. LE, "Follow-On Guidance for FY 2001 Interagency Research and Development Activities," June 8, 2000.

Within the CBDP, DTOs fund approximately 40% of S&T efforts in FY01. DTOs are the building blocks of the Defense S&T Program. They represent only high priority Service and Defense Agency programs, consistent with the Defense Planning Guidance and the Defense S&T Strategy. DTOs are one of the key S&T planning tools. They are used to assist in planning and programming S&T funds, they help in articulating key efforts and goals, and they provide a key performance measure for contribution of the S&T effort to warfighter needs. All updates, changes, and approvals of DTOs are made by the Defense Science and Technology Advisory Group (DSTAG), the senior S&T advisory body within the Department. Assessments of DTO performance are provided annually by the TARA.

The CBDP S&T efforts continue to demonstrate new capabilities for the warfighter. Progress of DTOs is shown in the following tables. Progress in other portions of S&T is shown in section 3.4.

3.3.1 Performance Indicator – Status of Defense Technology Objectives as Rated by the Chemical and Biological Defense Technology Area Review and Assessment				
	FY2001		FY2002	FY2003
	Goal	Actual	Goal	Goal
Percent of DTOs Rated Green (on track)	80	82*	80	80
Total Number of DTOs	21of 26	22 of 26*		

* 4 rated yellow

Table 3. 2001 TARA Rating of Chemical and Biological Defense DTOs

DTO No.	DTO Title	*TARA Rating*
I.02	Joint Biological Remote Early Warning System Advanced Concept Technology Demonstration (ACTD)	NOT RATED (NR) (COMPLETED)
I.03	Restoration of Operations (RestOps) ACTD	GREEN
L.12	Force Medical Protection (Chemical Biological Individual Sampler, CBIS) ACTD	GREEN
L.07	Terrorist CB Countermeasures	GREEN
CB.06	Advanced Lightweight Chemical Protection	NR (COMPLETED)
CB.07	Laser Standoff Chemical Detection Technology	GREEN
CB.08	Advanced Adsorbents for Protection Applications	GREEN
CB.09	Enzymatic & Catalytic Decontamination	GREEN
CB.19	Chemical Imaging Sensor	GREEN
CB.20	Biological Sample Preparation System for Biological Identification	GREEN
CB.22	Medical Countermeasures (CM) for Vesicant Agents	NR (COMPLETED)
CB.23	Medical CM for Staphylococcal Enterotoxin B	NR (COMPLETED)
CB.24	Medical CM for Encephalitis Viruses	YELLOW
CB.25	Multiagent Vaccines for Biological Threat Agents	GREEN
CB.26	Common Diagnostic Systems for Biological Threats and Endemic Infectious Disease	GREEN
CB.27	Therapeutics Based on Common Mechanisms of Pathogenesis	GREEN
CB.28	Chemical Agent Prophylaxis II	GREEN
CB.29	Active Topical Skin Protectant	GREEN
CB.30	Medical Countermeasures for Vesicant Agents II	GREEN
CB.31	Medical Countermeasures for Brucellae	GREEN
CB.32	Alternate (Needle-less) Delivery Methods for Recombinant Protein Vaccines	GREEN
CB.33	Recombinant Protective Antigen (rPA) Anthrax Vaccine Candidate	GREEN
CB.34	Recombinant Plague Vaccine	GREEN
CB.35	Standoff Biological Aerosol Detection	YELLOW
CB.36	Universal End-of-Service-Life Indicator for NBC Mask Filters	YELLOW

DTO No.	DTO Title	*TARA Rating*
CB.37	CB Agent Water Monitor	GREEN
CB.38	Activity Based Detection and Diagnostics	GREEN
CB.39	CW/BW Agent Screening and Analysis	GREEN
CB.40	Immune building program	YELLOW
CB.41	Biosensors	GREEN

3.3.1.1 Metric Description. Table 3 lists specific DTOs assessed during 2000. Appendix A to this section provides complete descriptions of the DTOs. Each DTO is reviewed annually by an independent peer review panel, called the Technology Area Review and Assessment (TARA) panel. The goal is to have at least 80% of the DTOs rated green. The total number of DTOs varies per year based on new DTO assignments and completion of DTO efforts. Total DTO funding varies per year and may represent between 25%–50% of total science and technology base funds. During the 2001 TARA, four DTOs were given a rating other than green. Following is a summary explanation for these ratings.

Table 4. Summary of Explanations for Selected 2001 TARA CB Defense DTOs

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.24, Medical Countermeasures for Encephalitis Viruses	YELLOW	• Weakness in the logic in thinking that the approach used for VEE would also work for EEE and WEE. • Concern that the vaccine construct may revert to wild type. It is not clear that a live attenuated vaccine is the only choice nor that this should be pursued as the optimal choice, especially since the DTO objectives are not going to be met. There are safety reasons to consider alternate strategies (*e.g.*, replicons).. • Complete work on Multivalent VEE, discontinue work on EEE/WEE, and terminate DTO.
CB.35, Standoff Biological Aerosol Detection	YELLOW	• No new technological approaches presented that could achieve the objective. • To avoid a potential RED rating next year, conduct a Front End Analysis (FEA) which focuses on new technological opportunities. Adjust DTO in accordance with FEA findings.
CB.36, Universal End-of-Service-Life Indicator for NBC Mask Filters	YELLOW	• Locked into reliance on a dated technology without full consideration of state-of-the-art technologies. Overall approach needs to be re-thought. Not clear whether the indicator intended to indicate the inactivity of the filtration media or the presence of contamination. Test design with simulants not validated, and may not allow for validation of technology. • Need to consider human factors (e.g., color at night?) • Apparent overemphasis on chemical rather than biological agents. Indicators being tested address failure due to chemical exposures. How would failure of HEPA filter be indicated? • No clear plan to test against live agent, TICs, or normal environmental contaminants for color changes. • Re-evaluate experimental design for testing. • Aggressively pursue multiple options for the 'indicator' approach.

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.40, Immune building program	YELLOW	• Not integrated with civil engineering community or human factors community. • Lacks engagement by DoD architecture-engineering (AE) community. • Does not have a technical review panel. • DTO's stated objectives may be conflicting (protection of occupants vs. timely restoration of building *vs*. preserving forensic evidence) • Water supply & food services not addressed. • Huge scope presenting a myriad of potential uncontrolled variables; results validation may be difficult. • Director, DARPA establish a technical oversight process with full engagement from the DoD AE community and the DoD civil engineering S&T participants – Joint Engineer Management Panel, Civil Engineering S&T Reliance Panel. *In response to TARA findings, DARPA documented a large number of community-wide interactions that started before the program was initiated; DARPA is committed to continuing and growing them throughout the program. DARPA has clarified why the scope does not include food and water (different threat mechanism requires different technical solution) and why objectives in conflict must be considered together (to enable end-to-end trades to be evaluated).*

3.3.1.2 V&V Methodology. Each TARA team includes about ten members, including experts from outside the Department. The non-DoD members include experts in relevant fields from other U.S. government agencies, private industry, and academia. S&T stakeholders (*e.g.*, senior S&T officials, the Joint Staff, and technology customers) attend the reviews as observers. TARA teams assess DTOs in terms of three factors—budget, schedule, and technical performance—and assign the programs a Red, Yellow, or Green rating based on how well they are progressing toward their goals. The assessment of technical performance includes a qualitative assessment of how risk is managed, especially for innovative or leading edge research that may involved high technical risk. This method of peer review is accepted and endorsed by the S&T stakeholders. Adjustments are made to program plans and budgets based on the ratings awarded. The following criteria are used in assigning ratings:

- Green – Progressing satisfactorily toward goals.
- Yellow – Generally progressing satisfactorily, but some aspects of the program are proceeding more slowly than expected.
- Red – Doubtful that any of the goals will be attained.

The DTO ratings are semi-quantitative metrics, reflecting the opinions of independent experts. The DTOs contain quantitative metrics, which provide a basis for determining progress of that effort towards a warfighter payoff.

3.4 BASIC RESEARCH (PROGRAM ELEMENT 0601384BP)

This program element (PE) funds the Joint Service core research program for CB defense (medical and non- medical). The basic research program aims to improve the operational performance of present and future DoD components by expanding knowledge in relevant fields for CB defense. Moreover, basic research supports a Joint Force concept of a lethal, integrated, supportable, highly mobile force with enhanced performance by the individual soldier, sailor, airman, or marine. Specifically, the program promotes theoretical and experimental research in the chemical, biological, medical, and related sciences. Research areas are determined and prioritized to meet Joint Service needs as stated in mission area analyses and Joint operations requirements, and to take advantage of scientific opportunities. Basic research is executed by academia, including Historically Black Colleges and Universities and Minority Institutions, and government research laboratories. Funds directed to these laboratories and research organizations capitalize on scientific talent, specialized and uniquely engineered facilities, and technological breakthroughs. The work in this program element is consistent with the *Joint Service Nuclear, Biological, and Chemical (NBC) Defense Research, Development, and Acquisition (RDA) Plan*. Basic research efforts lead to expeditious transition of the resulting knowledge and technology to the applied research (PE 0602384BP) and advanced technology development (PE 0603384BP) activities. This project also covers the conduct of basic research efforts in the areas of real- time sensing and diagnosis and immediate biological countermeasures. The projects in this PE include basic research efforts directed toward providing fundamental knowledge for the solution of military problems and therefore are correctly placed in Budget Activity 1.

3.4.1 CB Defense Basic Research (Project CB1)

This project funds basic research in chemistry, physics, mathematics and life sciences, fundamental information in support of new and improved detection technologies for biological agents and toxins; new and improved detection technologies for chemical threat agents; advanced concepts in individual and collective protection, new concepts in decontamination and information on the chemistry and toxicology of threat agents and related compounds.

3.4.1.1 CB1 Performance Goal (Outcome). The goal of the CB defense non-medical basic research program is to increase scientific understanding of the mechanisms and processes involved in the detection, protection against, and decontamination of chemical and biological warfare agents.

3.4.1.2 CB1 Outcome Measure

CB1 is minimally effective when	CB1 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – biosensors, – aerosol sciences, – chemistry and toxicology of bioactive compounds, – thin film technology development, – integrated detection of energetic and hazardous materials, – optical recognition technologies, – biological point detection, – protection – decontamination,	• Information, technologies, or processes are transitioned to applied research or advanced technology development

CB1 is minimally effective when	CB1 is successful when
– simulants, – information technology • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	

3.4.1.3 CB1 Actual and Planned Performance

FY2001 Targets	Actual Performance
<u>*Aerosol Science*</u> - Complete confirmation of the scattering model theorem by demonstrating imaging of biological cluster particles. Transition the technology to the applied research program for further development.	*Aerosol Science* - Continued validation of the scattering model theorem by demonstrating imaging of biological cluster particles
<u>*Biosensors*</u> - Perform DNA sequencing of the recognition elements to anthrax spores and SEB. Complete conjugate synthesis and chip integration of specific DNA/ fluorescent polymer conjugates. Demonstrate separation/ identification of dendrimer bound antibody/antigen couples via capillary electrophoresis.	*Biosensors*: • Targets met. In addition, high affinity aptamer for anthrax spores were isolated and cloned and are now being sequenced.
<u>*Chemistry and Toxicology of Bioactive Compounds*</u> - Continued studies of the percarbonate based decontaminant formulations by determining reaction product distributions and correlate equilibrium concentrations with solvent properties. Complete measurement of requisite adsorption rate data and begin development of a continuous adsorption model for filter performance. Establish new project to understand the toxicological mechanisms of one or two members of a class of potential new threat agents.	*Chemistry & Toxicology of Bioactive Compounds*: • Targets met. In addition, continued materials selection for molecular imprinting techniques in preparation for integration into a passive thin film chemical detection badge. Other research included (1) Thin Film Technology Development and (2) CB Agent Detection. *Thin Film Technology Development* - Continued development of semiconducting metal oxide thin film technology to detect chemical agents. Sought to minimize power requirements, weight, and volume with an overall intent to reduce burden to the individual user. Focused on approaches to maximize selectivity/ elimination of false alarms including mixed metal oxide films and nanocluster structures. Examined prefiltration/ preconcentration through chemical vapor deposition methods. Continued improvements in signal processing and control. *CB Agent Detection* - Conducted a multidisciplinary project to establish the proof of principle for detection methodologies and to develop detection systems for sensing the presence of CBW agents. Investigated development of a small- scale experimental detector for point detection of CW agents. Produced a design for a point detector to achieve highly specific and rapid detection of the CW agents in air using Ion Trap Mass Spectrometry (ITMS). This extremely sensitive type of mass spectrometer is particularly promising for in situ applications because of its small size and weight. Researched ITMS methodologies for

FY2001 Targets	Actual Performance
	the point detection of BW agents. Investigated neutron based CW detection.

3.4.1.4 CB1 Future Targets

FY 2002 Targets	FY 2003 Targets
Biosensors - Sequence Venezuelan Equine Encephalitis (VEE) aptamers and incorporate all available aptamers into Multiplex Electronic/Photonic Sensor (MEPS). Conduct optimization and assess miniaturization potential of the capillary electrophoresis detection system and validate concept. *Chemistry and Toxicology of Bioactive Compounds* - Construct "film badge" package to be used in the molecular imprinting technique for Individual Passive Chemical Agent Technologies and complete validation of concept for potential transition into 6.2 development. Conduct determination of rate laws for other organic oxidations using the new peroxide-based decontamination formulations. Complete development and validate filter model incorporating adsorption equilibria and dynamic behavior. Initiate a project to model filter performance concepts for individual protection systems. Expand pharmacokinetic and pharmacodynamic investigation to include additional new threat materials. *New Detection Technologies* – Initiate research on methods of combining chemical and biological agent detection on surfaces into one device. Include a variety of spectroscopic techniques focusing on portions of the electromagnetic spectrum not previously utilized for CB agent detection	*Biological Point Detection* - Continue investigations of novel technologies to detect and identify BW simulants and agents in environmental matrices. *Chemical Point Detection* - Continue efforts to detect CW agents using solid- state nano- arrays and analysis of degradation products. *Protection* - Continue investigations of self- assemblies for protective materials. *Decontamination* - Continue efforts to develop advanced decontamination materials to allow treatment of sensitive equipment, phase transfer materials, and solution chemistry. *Supporting Science* - Continue investigations of the behavior of CW agents and simulants under ambient environmental conditions. *Information Technology* - Continue efforts to directly couple information into warning system by neural coupling.

3.4.1.5 Assessment of CB Defense Basic Research. Basic research efforts in FY2001 for project CB1 are at least minimally effective. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects also were initiated in FY2001.

3.4.2 Medical Biological Defense Basic Research (Project TB1)

This project funds basic research on the development of vaccines and therapeutic drugs to provide effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. This project also funds basic research employing biotechnology to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include current science and technology program areas in medical biological defense (diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines) and directed research efforts (anthrax studies).

3.4.2.1 TB1 Performance Goal (Outcome). The goal of medical biological defense basic research is to increase scientific understanding of the mechanisms and processes involved in the pathogenesis of diseases caused by biological warfare (BW) agents, and the preventive, therapeutic, and diagnostic sciences underlying the technologies to counter these threats.

3.4.2.2 TB1 Outcome Measure

TB1 is minimally effective when	TB1 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – Bacterial Therapeutics, – Bacterial Vaccines, – Toxin Therapeutics, – Toxin Vaccines, – Viral Therapeutics, – Viral Vaccines, – Diagnostic Technologies, – Laboratory-based and Analytical Threat Assessment Research. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development

3.4.2.3 TB1 Actual and Planned Performance

FY2001 Targets	Actual Performance
<u>*Bacterial Therapeutics*</u> - Study host cellular and subcellular responses to BW threat agents (*B. anthracis, B. mallei, Y. pestis*) exposure to identify likely molecular targets for intervention by "next generation" (i.e., beyond present day) novel therapeutic strategies; evaluate possible generic intervention points in agent-induced pathophysiology. Assess broad spectrum therapeutic strategies for exposures to multiple BW threat agents. These strategies will focus on intervention in disease pathogenesis at the molecular level, and identify common host cellular targets for the pathogenic response. Develop methodologies utilizing biochemical (metabolic) processes for assaying in vivo antibiotic activity. Develop infection models in rodent species to evaluate antibiotic therapeutic indices.	<u>*Bacterial Therapeutics*</u>: • Most targets met. Did not complete assessment of broad spectrum therapeutic strategies for exposures to multiple BW threat agents.
<u>*Bacterial Vaccines*</u> - Investigate pathogenesis (cellular and molecular) and host immune responses; characterize additional virulence factors; define strain diversities; establish correlates of immunity for the causative agents of plague (Y. pestis), glanders (B. mallei), and anthrax (B. anthracis).	<u>*Bacterial Vaccines*</u>: • Targets met. In addition, identified potential host cell targets for a plague virulence factor and demonstrated mechanism of action in vitro of protective immunity against this virulence factor. Continued to evaluate live attenuated plague strains for their ability to elicit protective immunity. Demonstrated the importance of antibodies to an anthrax virulence protein in protecting host cells against killing by anthrax spores early in the infectious process. Investigated in vivo, the ability of licensed anthrax vaccine to protect against additional anthrax strains representing geographically diverse isolates. Characterized virulence genes in glanders strains that are responsible for encoding the organism's

FY2001 Targets	Actual Performance
	capsular virulence factor. Developed an in vitro model to examine interactions between Brucella and human monocyte cells. Compared the ability of Brucella lipopolysaccharide (LPS) to that of E. coli LPS for induction of cytokines.
Toxin Therapeutics - Identify sites of molecular action and mechanisms of intervention for therapies for botulinum toxin and SE threats; develop models for therapeutic intervention. Define endpoints for in vivo assessment of efficacy of therapeutic intervention for botulinum toxin and SE and surrogate endpoints of human clinical efficacy. Initiate high-output generation of candidate therapeutic moieties for botulinum and SE toxins using combinatorial chemistry.	*Toxin Therapeutics*: • Targets met.
Toxin Vaccines - Initiate studies to identify potential neutralizing epitopes in the translocation domains of the botulinum neurotoxins. Investigate the variability of clostridium botulinum strains in terms of their neurotoxic isoforms and the presence of other toxins produced by various strains. Initiate structural and biophysical characterization studies of recombinant protein vaccines antigens. Construct genetically engineered mutations of wild-type ricin A gene for the purpose of reducing enzymatic activity and solubility. Initiate evaluation of adjuvants that may enhance the host immune response to aerosol-administered vaccines and assess delivery vehicles that may enhance the uptake of aerosol-administered vaccines.	*Toxin Vaccines*: • Targets met.
Viral Therapeutics - Humanize mouse monoclonal antibodies specific for Ebola virus to test as an immunotherapeutic. Investigate mechanisms of filovirus transcription and replication focusing on polymerase as potential target for antiviral therapy.	*Viral Therapeutics*: • Targets met.
Viral Vaccines - Investigate the protective contribution of cytotoxic T cells in the Ebola virus mouse model. Investigate poxvirus immunity to determine if it is feasible to replace vaccinia immune globulin (VIG) with monoclonal antibodies and to construct a safe and effective vaccine to replace vaccinia virus vaccine for variola.	*Viral Vaccines*: • Targets met. Poxvirus immunity study confirmed hypothesis that vaccination with intracellular mature virus particles and extracellular enveloped virus immunogens is required for protection.
Diagnostic Technologies - Investigate new medical diagnostic technologies based upon state-of-the-art biotechnological approaches for the enhanced recognition of infections by validated biological threats (bacteria, viruses, and toxins) of military interest.	*Diagnostic Technologies*: • Targets met. Diagnostic technologies include new gene analysis chemistries and immunodiagnostics. Research also identified new biological markers and host responses that can be used for early recognition of infections including new primer and probe sets against new gene targets. Identified unique host immune markers using in vitro and in vivo models and developed primer and probe sets for these markers.

3.4.2.4 TB1 Future Targets

FY 2002 Targets	FY 2003 Targets
Diagnostic Technologies - Continue investigating new medical diagnostic technologies based upon state-of-the-art biotechnological approaches for the enhanced recognition of infections by potential biological threats (bacteria, viruses, and toxins) of military interest. *Bacterial Therapeutics* - Evaluate therapeutic indices for new (investigational) antibiotic agents identified by in vitro assays in suitable animal models. Study the effect of immunomodulators on the host response to B. mallei and Y. pestis candidate vaccines; identify those modulators that are effective in enhancing candidate vaccines. *Toxin Therapeutics* - Refine and standardize in vivo screening models for assessment of efficacy of therapeutic intervention in botulinum toxin and SE intoxication and standardize in vitro assays for neutralizing activity of lead inhibitors. Conduct high-output generation of candidate therapeutic moieties for botulinum and SE toxins using combinatorial chemistry. Evaluate inhibitor delivery strategies and demonstrate in vitro proof-of-concept. Begin high-throughput screening technology to investigate therapeutic candidates for exposure to ricin toxin. *Viral Therapeutics* - Determine the therapeutic potential of candidate drugs for treatment of disease for filovirus or orthopox infections. Characterize filovirus polymerases as potential antiviral drug targets and incorporate into in vitro assays *Bacterial Vaccines* - Obtain genetic sequencing data from a panel of validated threat agents; establish genetic sequences into a database; evaluate sequence data for the potential for genetic engineering and genetic modification of the pathogens; determine genetic fingerprints (genetic identifiers) of various isolates of the organism responsible for plague (Y. pestis), glanders (B. mallei), and anthrax (B. anthracis). Evaluate genetically modified strains of Y. pestis, B. mallei, and B. anthracis for their level of virulence in animals. Identify genes from Y. pestis, B. mallei, and B. anthracis that encode for novel virulence factors. Expand and characterize strain collections of bacterial threat agents; identify strains of various agents that may be resistant to existing vaccines and/or those under advanced development. *Toxin Vaccines* - Complete experiments involving the crystallization of vaccine candidates for structural studies and biophysical characterization of vaccines and toxins. Complete assessment of novel adjuvants and delivery vehicles for aerosol-administered vaccines. *Viral Vaccines* - Continue investigating poxvirus immunity to determine if it is feasible to replace VIG with monoclonal antibodies and to construct a safe and	*Diagnostic Technologies* - Identify new diagnostic approaches that can be applied broadly to the early recognition of infections. Technologies will be compatible with future comprehensive integrated diagnostic systems. *Bacterial Therapeutics* - Correlate metabolic measurements as a rapid and sensitive means to detect antibiotic activity with conventional susceptibility determinations and appropriate animal models of infection. Establish collaborative research and development agreements with interested pharmaceutical companies to test new and investigational antibiotics. Initiate evaluation of selected therapeutic compounds against brucella in vivo. *Toxin Therapeutics* - Complete high- output generation of candidate therapeutic moieties for botulinum and SEB toxins using combinatorial chemistry. Demonstrate in vivo proof- of- concept for integrated therapeutic approaches in botulinum toxin and SEB intoxication. Select lead ricin inhibitor and prepare toxin- inhibitor crystals for x- ray diffraction analysis. *Viral Therapeutics* - Develop intervention strategies for filovirus- induced shock and for therapeutic approaches that combine antiviral and antishock drug therapy. *Bacterial Vaccines* - Develop mutations in various agents for in vivo expressed genes to examine role in virulence. Characterize the mechanism(s) of vaccine resistance in selected strains of various agents. Determine mechanisms and correlates of protection with efficacious B. mallei vaccines. Evaluate differences in the course of brucella infection in different mouse strains. Test multiagent vaccine constructs for immunogenicity in higher animal species. *Toxin Vaccines* - Compare efficacy of constructs with neutralizing epitopes in other domains of botulinum neurotoxin serotypes E and F with the current subunit vaccine candidates. Evaluate vaccine candidates specifically designed to address host vulnerabilities identified in the lung. Develop vaccine candidates that protect against inhalationally induced incapacitation by selected toxin threat agents. *Viral Vaccines* - Complete investigating poxvirus immunity and determine the feasibility of replacing VIG with monoclonal antibodies and of constructing a new vaccine to replace vaccinia. *Anthrax studies* - Continue extramural research efforts toward the development and testing of new approaches for the treatment of inhalational anthrax. Focus will continue on two classes of compounds that inhibit the activity of the lethal toxin produced during anthrax

FY 2002 Targets	FY 2003 Targets
effective vaccine to replace the vaccinia virus vaccine for variola. *Anthrax studies* - Initiate development and testing of new approaches for the treatment of inhalational anthrax. Focus will be placed on two classes of compounds that inhibit the activity of the lethal toxin produced during anthrax infection and on a novel enzyme target, NAD synthetase, which is critical for the germination and vegetative life cycle of *B. anthracis*	infection and on a novel enzyme target, NAD synthetase, which is critical for the germination and vegetative life cycle of Bacillus anthracis.

3.4.2.5 Assessment of Medical Biological Defense Basic Research. Basic research efforts in FY2001 for project TB1 are at least minimally effective. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2001.

3.4.3 Medical Chemical Defense Basic Research (Project TC1)

This project emphasizes understanding of the basic action mechanisms of nerve, blister (vesicating), blood, and respiratory agents. Basic studies are performed to delineate mechanisms and sites of action of identified and emerging chemical threats to generate required information for initial design and synthesis of medical countermeasures. In addition, these studies are further designed to maintain and extend a science base. Categories for this project include science and technology program areas (Pretreatments, Therapeutics, and Diagnostics) and directed research efforts (Low Level Chemical Warfare Agent Exposure and Fourth Generation Agents).

3.4.3.1 TC1 Performance Goal (Outcome). The goal of medical chemical defense basic research is to increase scientific understanding of the mechanisms, processes, and effects of chemical warfare (CW) agents and the science involved in the detection, protection against, and decontamination of CW agents.

3.4.3.2 TC1 Outcome Measure

TC1 is minimally effective when	TC1 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – Toxicology of exposures to low levels of CW agents, – Pretreatments for chemical agent exposures, – Therapeutics for chemical agent exposures, – Novel threats (4th generation agents). • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development

3.4.3.3 TC1 Actual and Planned Performance:

FY2001 Targets	Actual Performance
Low Level - Begin filling identified data gaps on the pathological and behavioral effects of low-level CW nerve agent exposures. Investigate possible cellular mechanisms of low-level CW agent injury. Develop highly sensitive, forward deployable assay techniques to determine exposure to low levels of CW agents and subsequent physiological and toxicological effects.	*Low Level*: • Targets met.
Novel Threats (Fourth Generation Nerve Agents) - Determine mechanism by which novel threat agents produce toxicity that is not responsive to current nerve agent countermeasures.	*Fourth Generation Agents*: • Targets met. Information used to support studies in molecular modeling and site-directed mutagenesis.
Pretreatment - Complete evaluation of catalytic scavengers designed by site-directed mutagenesis. Develop candidate next generation pretreatments using knowledge gained from studies in molecular modeling and site-directed mutagenesis. Identify new candidate compounds with potential as pretreatment for vesicant injury based on current research strategies.	*Pretreatment*: • Targets met.
Therapeutics - Develop science base to identify specific factors leading to and/or preventing neuronal death in status epilepticus caused by nerve agents. Identify potential synergistic interactions of midazolam with anticholinergic drugs in rodent species. Define the optimal hypochlorite concentration for use in decontaminating chemical agent exposed skin and agent contaminated wounds.	*Therapeutics*: • Most targets met. Research on hypochlorite for skin decontamination not completed.

3.4.3.4 TC1 Future Targets

FY 2002 Targets	FY 2003 Targets
Pretreatments - Evaluate organophosphate anhydrolase for potential use as catalytic scavenger. Continue efforts to identify compounds for potential use as pretreatments for vesicant exposure. *Therapeutics* - Identify target sites for neuroprotection. Identify therapeutic targets for candidate compound combination therapies. *Low Level Chemical Warfare Agent Exposure* - Continue studies on identification of chronic pathological and behavioral effects of low level chemical warfare agent exposures. Investigate putative mechanisms of low level toxicity. Develop consensus for a coherent methodology for studies across endpoints and model species to permit integration of disparate endpoints, post-hoc analysis of research results, and extrapolation to nonhuman primate models. *Fourth Generation Agents* - Develop strategies to improve efficacy of current medical countermeasures against Fourth Generation Agents. Transition program to applied research	*Pretreatments* - Develop next generation pretreatments using knowledge gained from studies in molecular modeling and site- directed mutagenesis. Continue delineation of pathways of injury and potential pretreatment pharmaceutical intervention sites. *Therapeutics* - Incorporate biomarker panels into screening modules. Evaluate combination therapies for neuroprotection efficacy. Screen antidotes representing new strategies for counteracting deficiencies of medical countermeasures against Fourth Generation Agents. *Low Level Chemical Warfare Agent Exposure* - Continue studies of chronic neurological and/ or behavioral effects of chronic low level chemical warfare agent exposures. Identify potential toxic endpoints in low dose chemical warfare agent exposures. For verified endpoints, identify the mechanism(s) and biochemical pathway(s) involved in the generation of endpoint pathology.

3.4.3.5 Assessment of Medical Chemical Defense Basic Research. Basic research efforts in FY2001 for project TC1 are at least minimally effective. While there was no work completed in

basic research to investigate novel threat agents in FY2001, several studies have been initiated that will be continued through the next few years. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2001.

3.5 APPLIED RESEARCH (PROGRAM ELEMENT 0602384BP)

The use of chemical and biological weapon systems in future conflicts is an increasing threat. Funding under this PE sustains a robust program, which reduces the danger of a CB attack and enables U. S. forces to survive and continue operations in a CB environment. The medical program focuses on development of vaccines, pretreatment an d therapeutic drugs, and on casualty diagnosis, patient decontamination, and medical management. In the non- medical area, the emphasis is on continuing improvements in CB defense materiel, including contamination avoidance, decontamination, and protection systems. This program also provides for conduct of applied research in the areas of real- time sensing and immediate biological countermeasures. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. Efforts under this PE transition to and provide risk reduction for Advanced Technology Development (PE 0603384BP), Demonstration/ Validation (PE 0603884BP), and Engineering and Manufacturing Development (PE 0604384BP). This project includes non- system specific development directed toward specific military needs and therefore is correctly placed in Budget Activity 2.

3.5.1 Chemical and Biological Defense Applied Research (Project CB2)

This project addresses the urgent need to provide all services with defensive materiel to protect individuals and groups from CB threat agents in the areas of detection, identification and warning, contamination avoidance via reconnaissance, individual and collective protection, and decontamination. The project provides for special investigations into CB defense technology to include CB threat agents, operational sciences, modeling, CB simulants, and nuclear, biological, chemical (NBC) survivability. This project focuses on horizontal integration of CB defensive technologies across the Joint Services. The Defense Technology Objectives (DTOs) provide a means to shape the development of selected technologies within this project.

3.5.1.1 CB2 Performance Goal (Outcome). The goal of the CB defense non-medical applied research program is to increase scientific understanding of the mechanisms and processes involved in chemical and biological warfare (CBW) agents and potential applications of this information for the development of advanced technologies for the detection, protection against, and decontamination of CBW agents.

3.5.1.2 CB2 Outcome Measure

CB2 is minimally effective when	CB2 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – biosensors for point detection and early warning, – critical reagents for biological agent detection & identification, – aerosol sciences, – threat agents,	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA Panel.

CB2 is minimally effective when	CB2 is successful when
– agent dispersion and fate modeling, – advanced materials for individual protection, – advanced methods and materials for decontamination, – chemistry and toxicology of bioactive compounds, – man portable thin film technology, – integrated detection of energetic and hazardous materials, – optical recognition technologies, – new detection technologies. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	

3.5.1.3 Metric Description. The metric for CB2 is described in Section 3.2.1.1. Applied research also includes several specific projects that are identified as Defense Technology Objectives (DTOs), which are detailed and assessed separately (See section 3.3). DTOs funded under this project include the following:

- Bio Sample Preparation System (BSPS)
- Chemical Imaging Sensor
- Advanced Adsorbents for Protection Applications
- Enzymatic Decontamination
- Standoff Biological Aerosol Detection
- Universal End-of-Service-Life Indicator for NBC Mask Filters
- CB Agent Water Monitor
- Environmental Fate of Agents
- CB Warfare Effects on Operations
- Oxidative Decontamination Formulation
- Self-Detoxifying Materials for CB Protective Clothing

3.5.1.4 CB2 Actual and Planned Performance:

FY2001 Targets	Actual Performance
<u>*Supporting Science and Technology*</u> - Complete first toxicology study using highly toxic powder in the new (first and only in the US) nose-only exposure chamber for extremely hazardous aerosols. Measure quantitative performance of candidate aerosol collectors for advanced point biodetection technology. Demonstrate a new aerosol collector using mini-scale manufacturing technology which reduces power consumption at least a factor of 4 below JBPDS with high collection efficiency (>80%) over the particle size range from 1-10 micrometers diameter and operates at the Joint Service low temperature requirement (-28ºF). Continue to provide controlled biosimulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for the JFT.	<u>*Supporting Science and Technology*</u>: • Targets met
<u>*Biological Point Detection*</u> - Complete analysis of accumulated ambient data and identify gaps for further study as indicated by analysis. Continue generation and screening of recombinant antibodies against select bioagents using Biased libraries.	<u>*Biological Point Detection*</u>: • Targets met

FY2001 Targets	Actual Performance
Incorporate into Enzyme Linked Immuno Sorbent Assay (ELISA), biosensors for test and transition best candidates to Critical Reagent Program. *Modeling and Simulation* - Continue model development for simulation of CBW effects on joint force operations for incorporation into advanced simulations like [Joint Conflict and Tactical Simulation (JCATS), Joint Simu lation System (JSIMS), Joint Modeling and Simulation System (JMASS), and Joint Warfare System (JWARS)]. Continue development of coupled CB environment/ meteorological models for incorporation of CBW hazard prediction/tracking into forward-deployed meteoro logical forecast/nowcast operations. Continue development of advanced CBW environment models for more accurate, higher-resolution atmospheric transport and fate predictions in complex and urban terrain for battle space awareness and contamination avoidance. Continue development of models for Joint Service CB defense equipment for application in SBA. Continue development of the Simulation, Training and Analysis for Fixed Sites (STAFFS) model for simulation of CBW effects on operations at Aerial Ports of Debarkation (APOD) and Sea Ports of Debarkation (SPOD). *Low Level Chemical Agent Operational Studies* - Complete sarin data analysis on rats. Initiate miosis threshold studies using sarin over extended exposure durations. Initiate potency ratio studies of second generation nerve agents for toxicological effects of extended exposure duration and low concentration exposures to validate and verify alarm and warning levels/thresholds for detector systems *Leap Ahead Technologies* - Investigate advanced respiratory and percutaneous protection technologies (FY00 Individual Protection, Front End Analysis) to reduce thermal load and breathing resistance. Break technology barriers in developing simulants for emerging agents. Complete Force Amplified Biosensor (FAB). Refine discrimination algorithms and chamber test optical fluorescence/shape analysis and pyrolysis -gas chroma tography-ion mobility spectrometry. These approaches are candidates for Joint Modular Chemical and Bio logical Detector System (JMCBDS), capable of downsizing and providing classification among bio particles. Complete initial analysis of radar multi-mission sensor and identify other disparate sensors. Initiate assessment of data gaps in threat agent data and needs for improved simulants in CB defense materiel development. Institute a simulant data base for selecting appropriate simula nts in materiel development and establish a repository for chemical simulants and a standard biosimulant laboratory. *Individual Protection* - Select and evaluate permselective membranes to validate the novel permselective membrane model. Investigate mechanisms for more durable nanofibers, and fabricate and test samples of those materials. Investigate nanofiber bonding/ integra tion methods, and conduct aerosol and challenge tests. Identify methodology for evaluation of suits against TICs. Construct a parametric skeleton model of candidate helmet/mask concepts to help identify those with most potential for long term solutions. Construct and evaluate proof of principle End of Service	*Modeling and Simulation*: • Targets met. In addition, completed validation studies and software documentation for Va por, Liquid, Solid Tracking (VLSTRACK) version 3. *Low Level Chemical Agent Operational Studies*: • Targets met *Leap Ahead Technologies*: • Targets met. In addition, initiated exploration of chip-based phylogenetic assay for highly multiplexed biological agent detection. *Individual Protection*: • Targets met. ELSI status listed with DTO description in appendix.

FY2001 Targets	Actual Performance
Life Indicator (ESLI) model. *Collective Protection* - Conduct a Front-End Analysis and prepare a Master Plan to help focus investment in Collective Protection technologies and to ensure warfighter needs are met. Complete Residual Life Indicator (RLI) sensor side-by-side testing, and complete simu lant, TIC, and agent testing of candidate sensors. Pro duce and test immobilized beds for selected applica tions using optimized materials and processes. Complete the acquisition of breakthrough and equilibrium data of current adsorbents against TICs and assess adsorptive/ chemisorptive properties. Conduct lab scale testing to validate the Pressure Swing Adsorption model and to help in optimizing the bed/system performance of regen erative filtration systems. Produce and evaluate optimized hermetic seals for shelters, and transition to Joint Transportable Collective Protection System (JTCOPS). *Decontamination* - Complete demonstration of sensitive equipment decontamination methodology and finalize transition of technology for Block I of the JSSED pro gram. Select technologies to be demonstrated for sensitive interiors (JSSED Block II) focusing on thermal approaches. Evaluate approaches for operational decontamination of sensitive equipment and interiors on the move (JSSED Block III). Augment enzymatic decontamination program using alternative academic based approaches to improve efficiency of V-agent enzymes and transfer this technology into the DTO for evaluation. Broaden the scope of enzymatic decontamination processes evalu ating potential systems for non-traditional agents. Vali date oxidative processes in aqueous and mixed/aqueous/organic solvent systems as either solutions, emulsions or microemulsions. Examine dendritic assembly systems incorporating mono-ethanol amine functionality and perform preliminary agent challenges. Focus solution based approaches on developing formulations using the best combinations of technical approaches. Continue evaluation of novel solid matrices. Initiate an effort to determine the fundamental limitations of solid based approaches. Evaluate the possibility of combining these novel solid materials into other application systems. Complete participation in the working group revising North American Treaty Organization (NATO) Triptych D.102 on Decontamination. Continue efforts to detemine the fate of agent on common environmental surfaces associated with fixed site facilities. Conduct study to evaluate the hazard posed by potential reaero solization of BW materials. Determine an approach to use coating technology to address decontamination and protection of materiel items. *Early Warning Detection* - Initiate development of enhanced discrimination algorithms for optical fluorescence/shape analysis and pyrolysis -gas chroma tography -ion mobility spectrometry through use of chamber and/or field tests with bioagent simulants. Complete initial analysis and utility assessment of radar multimission sensor as CB event queuing approach. Identify other disparate sensors capable of providing or enhancing battlefield awareness of CB events and initiate utility assessment in validated model.	*Collective Protection*: • Targets met. The FEA/ MP identified and prioritized various DoD user community requirements for Collective Protection. Various filtration and shelter technology approaches were identified, categorized and prioritized in terms of maturity, risk, applicability, and cost. *Decontamination*: • Most targets met. Transferred oversight of the fate of agents and the reaerosolization of BW materials to Supporting Science and Technology Business Area. Did not initiate an effort to determine the fundamental limitations of solid based approaches. Evaluate the possibility of combining these novel solid materials into other application systems. Complete participation in the working group revising NATO Triptych D.102 on Decontamination. Did not determine an approach to use coating technology to address decontamination and protection of materiel items. The coatings effort determined that potential coatings technology approaches are not mature enough to pursue at this time. *Food and Water* - Evaluated alternative technologies; e.g., surface enhanced RAMAN, molecular imprinted polymers, gas chromatograph- ion mobility spectrophotometer for risk reduction in support of the Joint Chemical Biological Agent Water Monitor (JCBAWM).

FY2001 Targets	Actual Performance
Chemical Point Detection - Complete breadboard design with integration of both chemical and biological contaminant detection capabilities. Continue the breadboard hardware build and initiate planning for demonstration of the water monitor. *Biological Standoff Detection* - Initiate analysis of existing data to identify top candidates for further evaluation to provide improved bio standoff capability. Identify and develop key performance requirements to meet biological standoff capability.	*Man-portable Detectors* - Continued insertion of semi-conductive metal oxide (SMO) technology (and Surface Acoustic Waves (SAWs) if required) into a chemical detector brassboard. Based on user inputs, determined the operational parameters of a man-portable detection system. Joint Service requirements were used to determine the response parameters and operating environment. Demonstrated an integrated prototype detector system for CW agents under laboratory and field conditions. *Improved CB Detection* - Enhanced performance of high sensitivity passive stand-off detector by increasing hardware sensitivity, characterizing and removing background variables, and improving system detection software. *CB Countermeasures* - Completed first year research in CB Countermeasures with 25 diverse tasks in CB detector development, CB medical toxicology and vaccine research, fast detection methods for biological contaminants in food, new protective materials development, novel decontamination methods, novel blood assays for biologicals, improved methods for WMD first responders, improved hospital response techniques and modeling of biological contamination spread. Awarded second year follow on contracts to successful first year projects. Initiated eight new CB countermeasure projects in biotechnology and fast sensor development.

3.5.1.5 CB2 Future Targets

FY 2002 Targets	FY 2003 Targets
Biological Point Detection - Reduce size and logistic burden of optical fluorescence/shape analysis system and Py-GC-IMS sensors. Test against expanded set of biological simulants and interferents. Initiate exploration of new concepts for small, combined chemical and biological identifiers. Develop and test concepts toward automation of chip-based phylogenetic analysis of biological materials. Develop database of multiple gene targets for biological agents. Identify and initiate exploration of other concepts for multiplexed identification/analysis of broad spectrum of biological agents. Continue generation and screening of recombinant antibodies against select biological agents, and transition best candidates to Critical Reagents Program. Initiate biological background data collection efforts to fill data gaps previously identified	*Supporting Science and Technology* - Complete the assessment of long term needs in threat agent data and needs for improved simulants in CB defense materiel development, and participate in a collaborative inter-agency laboratory program to fill the data gaps and improve simulants. Continue to synthesize, toxicologically screen and characterize identified new threat materials and to fill identified data gaps for established threats, including FGAs. Continue development of improved simulants for threat CB materials. Continue to measure quantitative performance of candidate aerosol collectors for advanced point biological detection technology. Fabricate and test the first brassboards of a new generation of aerosol concentrators and collectors using micro-machining technology to reduce the size, power consumption, and weight of aerosol components in order to meet the

FY 2002 Targets	FY 2003 Targets
Collective Protection - Determine TIC breakthrough and equilibrium data for advanced and novel adsorbents. Conduct prototype (large diameter bed) regenerative filter bed testing to demonstrate bed improvements and to update the performance model. Develop novel singlepass filter concepts using nano-materials and identify absorbents to support that concept. Evaluate shelter materiel using technologies identified to facilitate rapid development of an improved product. *Modeling and Simulation of Joint Operability* - Expand model development for simulation of CBW effects on joint force operations for incorporation into advanced simulations. Demonstrate operational capability of the STAFFS model for simulation of CBW effects on operations at APODs and SPODs. *Modeling and Simulation of CBW Environment* - Expand development of advanced CB weapons models (Lagrangian particle and complex fluid dynamics methodologies) for more accurate, higher-resolution atmospheric transport and fate predictions in complex and urban terrain for battlespace awareness and contamination avoidance. Extend development of high-altitude CB agent behavior for application in Tactical Ballistic Missile (TBM) intercept analysis. Begin development of the capability to accurately model the interaction (evaporation and persistence) of chemical agents with materials and the reaerosolization of biological agents. *Supporting Science and Technology* - Continue assessment of gaps in threat agent data, and identify needs for improved simulants in CB defense materiel development. Initiate a program of synthesis, toxicology screening, and characterization of new threat materials (to include Fourth Generation Agents (FGAs)) identified as urgent needs while continuing assessment of long-term needs. Initiate development of improved simulants for chemical aerosols, microencapsulated viruses, stabilized bacteria, and proteinaceous and nonproteinaceous toxins/ bioregulators. Continue to measure quantitative performance of candidate aerosol collectors for advanced point biological detection technology. Initiate the design of a new generation of aerosol concentrators and collectors using micro-machining technology to reduce size, power consumption, and weight, in order to meet stringent requirements for advanced miniature detection systems. Initiate design of advanced aerosol inlets to meet Joint Service requirements for high collection efficiency over the respirable particle size range at wind speeds up to 60 mph. Continue to provide controlled biological simulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for the JFT. Assemble a database on agent fate on surfaces	stringent requirements for advanced detection systems. Fabricate and test the first brassboards of advanced aerosol inlets to meet Joint Service requirements for high collection efficiency over the respirable particle size range and for wind speeds up to 60 mph. Continue to provide controlled biosimulant aerosol challenges and begin providing chemical agent simulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for the JFT. *Detection of Contaminants on Surfaces* - Downselect the most mature technology. Design and build a breadboard system to demonstrate the technology to detect the presence of CBW contaminants (including FGAs) on surfaces. *Individual Protection* - Complete evaluation of the level of chemical protection provided by fielded/ developmental clothing materials against TICs. Develop methodology to facilitate testing of all candidate materials. Produce first generation membranes with ion optimized properties, and evaluate for enhancements in permselectivity. Evaluate adsorbent placement in semipermeable membrane garments using the clothing energy/ mass transport model, and produce and test a concept model to validate adsorbent placement. Complete model for the characteristics and performance of advanced mask air filtration/ purification concepts and produce an advanced prototype based on the results. *Modeling and Simulation of Joint Operability* - Continue model development for simulation of CBW effects on joint force operations for incorporation into advanced simulations. Improve capability of the STAFFS model for simulation of CBW effects on operations at APODs and SPODs, by incorporating new databases for fixed site operations [*e.g.*, Restoration of Operations, (RestOps)], and demonstrate final operational capability. *Modeling and Simulation of CB Defense Equipment* - Continue development of models for Joint Service CB defense equipment for application in Simulation Based Acquisition (SBA) training, distributed simulations, wargaming, and military worth evaluations. *Decontamination* - Demonstrate technology solutions for transition to JSSED Block II and III. Optimize formulations for chemical and biological decontamination systems and evaluate against agents. Develop and demonstrate novel solid sorbent technology. Identify data gaps in agent fate and initiate studies to produce additional data required by the CB community. *Low Level Chemical Agent Operational Studies* - Complete G agent potency ratio studies on rats. Continue multi- species animal studies for G- series agents. Complete planning and initiate efforts for V-

FY 2002 Targets	FY 2003 Targets
incorporating prior year's findings. Complete BW reaerosolization studies. *Detection of Contaminants on Surfaces* - Initiate a program to develop technology to detect the presence of CBW contaminants on surfaces, for use in vehicular and handheld systems. Initial studies will focus on active and passive optical technologies that could be employed on or from a vehicular platform. *Chemical Point Detection* - Test/demonstrate the capabilities of the high potential alternative technologies from the technical evaluation of technology conducted in FY01 for the JCBAWM effort. *Modeling and Simulation of CB Defense Equipment* - Expand development of models for Joint Service CB defense equipment for application in Simulation Based Acquisition (SBA) training, distributed simulations, war-gaming, and military-worth evaluations. *Early Warning Detection* - Demonstrate concept and technology of a test representative RADAR system for queuing of stand off systems. Investigate options for linking disparate sensors to battlespace management systems. *Individual Protection* - Incorporate aerosol threat mediation techniques in the fabrication of concept garments. Initiate testing of concept garments. Identify and incorporate color transition materials into nano-fiber membranes and test for response to agent simulants. Evaluate fielded and developmental clothing materials for the protection they provide against TICs. Produce trial membranes using ion implantation techniques, and evaluate their material physical properties and agent protection capabilities. Conduct a study of adsorbent fabric placement in semi-permeable membrane garments for added vapor and aerosol protection. Fabricate and evaluate a proof of concept model of the helmet/mask concept using the parametric skeleton model. Construct and evaluate prototype mask end of service life indicators. Initiate development of advanced concepts in mask air filtration/purification. *Decontamination* - Continue developmental efforts to address JSSED Block II and III approaches focusing on thermal technology and spot cleaning methodology. Develop solution approaches for Superior Decontamination Systems combining novel chemical and biochemical technologies into a unified approach. Complete the evaluation determining the physical limitations of novel solid technology and implement findings into the program. Determine best future uses for these materials *Low Level Chemical Agent Operational Studies* - Complete miosis threshold studies for sarin over	series agents in rats. Continue physiological modeling efforts to understand the dependence of toxicological effects on the route of exposure to low level nerve agents. *Early Warning Detection* - Develop architecture to support and implement disparate sensor concepts into battlespace management capabilities. *Wide Area Detection* - Improve the sensitivity of the Chemical Imaging Sensor with integration of high sensitivity passive infrared technology. Provide the next generation of passive detection system with 10- 100 fold improvement in sensitivity in comparison to current developmental systems. *Collective Protection* - Fabricate and test candidate nano material adsorbents for novel single pass filter concepts to determine their performance characteristics. Initiate development of technologies leading to self-decontaminating soft wall shelters. *Modeling and Simulation of CBW Environment* - Complete development of advanced CBW environment models for more accurate, higher- resolution atmospheric transport and fate predictions in complex and urban terrain for battlespace awareness and contamination avoidance. Incorporate source terms for new and emerging threats. Complete development, validation and verification studies of high- altitude CB agent behavior for application in TBM intercept analysis. Continue development of the ability to accurately model the interaction (evaporation and persistence) of chemical agents with materials and the reaerosolization of biological agents. *Biological Identification* - Continue biological background data collection efforts to fill data gaps previously identified. Continue development and testing automation of chip- based phylogenetic analysis of biological materials. Complete feasibility study to determine technological issues associated with microwave spectroscopy of biological materials under ambient conditions. Integrate concepts in protein separation and concentration technology to increase sensitivity and reduce interference from background materials into electrospray ionization mass spectroscopy. *Reagents* - Continue development of database and validation methodology for multiple gene target reagents for biological agents. Laboratory demonstrate Quantum Dot technology for application to enhance antibody ticket technology for improved stability and sensitivity. Downselect and laboratory demonstrate combinatorial peptides as biological recognition elements as candidate replacements against traditional reagents. Continue the standardization of biological simulant materials for test and evaluation efforts.

FY 2002 Targets	FY 2003 Targets
extended exposure durations. Continue G agent potency ratio studies on rats. Initiate multi-species animal studies for G agents. Initiate planning for third generation nerve agents studies in rats. Initiate physiological modeling efforts to understand the dependence of toxicological effects on the route of exposure to low level nerve agents. *FGA (non-medical)* - Modify point detection systems to enhance performance against new chemical targets and characterize effect of modifications on performance to existing chemical targets and on interference rejection. Broaden spectral knowledge base in order to predict performance of active and passive IR sensors for detection of surface contamination. Examine novel materials and material treatment solutions to decrease penetration of aerosol particulates through overgarments. *Biological Standoff* - Investigate novel approaches to detection and discrimination of biological aerosols in standoff mode. Examine application of improved laser sources and methodologies and develop spectral database and methodologies to support assessment of new approaches such as Brillouin scattering, Mueller matrix LIDAR, millimeter wave spectroscopy. Investigate potential applicability of UV and IR imaging. *Agent Fate* - Identify standard construction and natural environmental materials and study interactions of these materials with chemical agents using novel in situ methods. Develop refined laboratory methodologies to support these studies. Define previously unaccounted environmental loss mechanisms and provide results for improvement of hazard modeling. Refine relevant physical property data relate to chemical hazard evolution. *CB Modeling/Simulation* - Enhance spatial resolution of hazard prediction codes through physical models that incorporate resolution improvements in radiation, turbulence, and precipitation physics. Initiate coupling of numerical weather prediction models with existing CBW dispersion codes.	*Integrated CB Point Detection* - Continue exploration of new concepts for small, combined chemical and biological identifiers. Expand feasibility studies on "low consumable or reagentless" concepts. *Aerosol Agent Rapid Detection* - Downselect techniques and initiate breadboard design with aerosol sample processing. *Agent Fate* - Determine VX fate on concrete under lab conditions. Initiate GD fate on sand and grass. Select and characterize thickened agent formulations. Refine model structure to incorporate concrete matrix substrate parameters and initiate prediction analysis for field validation studies for FX. Initiate validation and extend laboratory studies using field protocols.

3.5.1.6 Assessment of Chemical and Biological Defense Applied Research. Applied research efforts in FY2001 for project CB2 are at least minimally effective. Many areas of CB defense applied research were successful. The assessment is based on two factors: (1) two DTOs in this area was rated yellow by the TARA. Both efforts have developed plans to address concerns identified and will be re-assessed in FY2002. (2) Several technologies successfully transitioned to advanced development, including reagent development, modeling and simulation, and collective protection materials. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2001.

3.5.2 Medical Biological Defense Applied Research (Project TB2)

This project funds applied research on the development of vaccines, therapeutic drugs, and diagnostic capabilities to provide an effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. Innovative biotechnological approaches and advances will be incorporated to obtain medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include Defense Technology Objectives (DTO); science and technology programs in medical biological defense (diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines); and directed research efforts (medical countermeasures, genetically engineered threat countermeasures, and vaccines).

3.5.2.1 TB2 Performance Goal (Outcome). The goal of CB defense medical biological defense applied research is to increase scientific understanding of the mechanisms and processes involved in the pathogenesis of BW agents in order to develop preventive and therapeutic protection and diagnostic technologies for BW agents.

3.5.2.2 TB2 Outcome Measure

TB2 is minimally effective when	TB2 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – Bacterial Therapeutics, – Toxin Vaccines, – Bacterial Vaccines, – Toxin Therapeutics, – Viral Therapeutics, – Viral Vaccines, – Diagnostic Technologies, and – Protocols to Enhance Biological Defense. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA Panel.

3.5.2.3 Metric Description. The metric for TB2 is described in Section 3.2.1.1. Applied research also includes several specific projects that are identified as Defense Technology Objectives (DTOs), which are detailed and assessed separately (See section 3.3). DTOs funded under this project include the following:

- Medical Countermeasures for Encephalitis Viruses
- Multiagent Vaccines for Biological Threat Agents
- Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases
- Medical Countermeasures for Brucellae
- Alternate (Needleless) Delivery Methods for Recombinant Staphylococcal Enterotoxin (SE) Vaccines
- Recombinant Protective Antigen (rPA) Anthrax Vaccine Candidate
- Recombinant Plague Vaccine

3.5.2.4 TB2 Actual and Planned Performance:

FY2001 Targets	Actual Performance
Bacterial Therapeutics - Optimize animal models for therapeutic indices; evaluate in vivo activity of selected antimicrobials in established in vitro biochemical assays. Evaluate next generation antibiotics for therapeutic efficacy against bacterial threat agents.	*Bacterial Therapeutics*: • Targets met. In addition, designed an animal model for in vivo evaluation of selected compounds to protect against parenteral and aerosol infection by glanders and anthrax bacteria. Performed in vivo studies to evaluate therapeutic compounds against glanders.
Bacterial Vaccines - Evaluate previously identified virulence factors as vaccine candidates for Y. pestis. Optimize the animal model for aerosol exposure to B. mallei (glanders) for use in assessing vaccine candidates. Complete research on existing surrogate markers of protection against plague; identify surrogate markers for anthrax and additional markers for plague.	*Bacterial Vaccines*: • Targets met. Research on additional markers included demonstrating surrogate efficacy in the mouse model against aerosol plague infection by passive transfer of F1 capsular and V antigen antibody. Also, demonstrated surrogate efficacy in the rabbit model against parenteral anthrax infection by passive transfer of rPA antibody. In addition, obtained plasmids to carry foreign genes for constructing vaccine strains in avirulent rough mutants of brucella in order to evaluate brucella as a possible multiagent vaccine platform.
Toxin Therapeutics - Standardize assays for high-throughout screening of small molecule inhibitors of botulinum and SE toxin ligand-receptor interaction.	*Toxin Therapeutics*: • Targets met. In addition, developed a cell-free enzymatic assay for ricin toxicity and screening inhibitors and developed a quantitative ricin neutralization assay to evaluate immune response in humans following vaccination. Solved three dimensional structure of the bound and unbound serotype B botulinum neurotoxin (BoNT) by x-ray crystallography to better characterize the active site for inhibitor development. Established a transgenic mouse colony and showed that lymphocytes from the mice react similarly to human lymphocytes to various biological warfare agents. Generated panels of monoclonal antibodies that neutralize BoNT serotype A and SE serotypes A, B, C1, and D.
Toxin Vaccines - Express recombinant vaccine candidates for botulinum toxin serotypes D and G in the Pichia yeast system and initiate efficacy studies.	*Toxin Vaccines*: • Targets met.
Viral Therapeutics - Develop a rabbitpox-rabbit animal model for analysis and characterization of candidate antiviral compounds for therapeutic activity. Investigate mechanisms of Ebola and Marburg virus (MBGV) pathogenesis in nonhuman primate models to define likely targets in agent pathogenesis and identify potential mediators of shock.	*Viral Therapeutics*: • Targets met.
Viral Vaccines - Explore the addition of cytokine gene co-delivery with Ebola viral genes to achieve protective immunity. Determine the components required in a vaccine that will protect against the most divergent isolates of MBGV.	*Viral Vaccines*: • Targets met.
Diagnostic Technologies - Prepare new diagnostic reagents and devices compatible with emerging immunological platforms and rapid nucleic acid analysis systems for enhanced	*Diagnostic Technologies*: • Targets met

FY2001 Targets	Actual Performance
recognition of infections with validated biological threats. Evaluate medical diagnostic technologies and specimen-processing methods compatible with a comprehensive integrated medical diagnostic system for the rapid recognition of infections by validated biological threats (bacteria, viruses, and toxins) of military interest. Identify field sites for the comprehensive validation of rapid diagnostic methods that will provide performance data prior to transitioning to advanced development	• Targets met.

3.5.2.5 TB2 Future Targets

FY 2002 Targets	FY 2003 Targets
Diagnostic Technologies - Prepare diagnostic reagents that will enhance the depth and diversity of current approaches for the rapid recognition of infection by potential biological threat agents. Evaluate preclinical models and standards for evaluating medical diagnostic systems prior to transition to the regulatory-compliant medical laboratory. *Bacterial Therapeutics* - Optimize and correlate in vitro assays with animal models for selected antibiotic and nonantibiotic therapeutics for bacterial threat agents; examine effects of selected therapies on multiple agent exposures in an animal model. *Toxin Therapeutics* - Initiate structural stabilization and formulation studies on lead inhibitors of botulinum and SE toxin activity. Refine in vivo and standardize in vitro screening models for botulinum toxin and SE intoxication. *Viral Therapeutics* - Assess the potential for immunotherapy against Ebola virus in nonhuman primate models. Complete investigation of mechanisms of Ebola and MBGV pathogenesis in nonhuman primate models to characterize promising surrogate markers of efficacy for therapies. *Bacterial Vaccines* - Optimize in vitro correlate assays for candidate vaccines against various bacterial threat agents; evaluate the efficacy of additional novel component vaccine candidates (i.e., fusion proteins and antigen cocktails). Optimize formulation and dosage regime of selected vaccine candidates in animals. *Toxin Vaccines* - Determine whether the recombinant fragment C vaccine candidates can elicit protective immunity in mice against neurotoxins produced by various strains of Clostridium botulinum. *Viral Vaccines* - Define the correlates of immunity (i.e., neutralizing antibody, cytotoxic T cells) that protect against disease from MBGV. Develop assays to measure "surrogate markers" to validate the efficacy of vaccine candidates in established model systems for MBGV.	*Diagnostic Technologies* - Evaluate overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of detecting and identifying a broad range of biological threat agents in clinical specimens. Design and evaluate new medical diagnostic technologies and specimen- processing methods for the enhanced recognition of infections by potential biological threat agents by field medical laboratories. Continue to evaluate diagnostic technologies by using animal models. Develop field sites for evaluating new diagnostic technologies. *Bacterial Therapeutics* - Evaluate novel antibiotics and nonantibiotic therapeutics in established in vitro assays and animal models. Establish a database of therapeutic profiles for various strains of bacterial threat agents. *Toxin Therapeutics* - Evaluate the outcome of structural stabilization studies on lead inhibitors of botulinum and SE. Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy. *Viral Therapeutics* - Continue assessing the potential for immunotherapy against Ebola virus in higher animal species models. Identify pharmacological compounds provided by industry that may disrupt filovirus polymerases. Assess therapeutic action of compounds in mouse and higher animal models of filovirus infection. *Bacterial Vaccines* - Develop mutants in various agents for in vivo expressed genes to examine role in virulence. Characterize the mechanism(s) of vaccine resistance in selected strains of various agents. Determine mechanisms and correlates of protection with efficacious B. mallei vaccines. *Toxin Vaccines* - Standardize in vivo and in vitro concept model systems for assessment of vaccine efficacy and surrogate endpoints of human clinical efficacy. *Viral Vaccines* - Define the correlates of immunity that protect against disease from Ebola virus. Develop assays to measure surrogate markers to validate the efficacy of

FY 2002 Targets	FY 2003 Targets
Vaccines - Enhance applied research toward innovative approaches for the development and delivery of next generation and generation-after-next vaccines and strategies to enhance the immune response to broad classes of biological threats. *Medical Countermeasures* - Enhance applied research efforts toward the development of broad-spectrum therapeutic countermeasures for exposure to broad classes of biological threats. *Genetically Engineered Threat Medical Countermeasures* - Expand genetic and protein databases to identify and catalogue the various virulence factors, toxic motifs and host regulatory proteins responsible for the pathologic effects of biological threat agents. Continue research efforts such as curating the genetic information base, evaluating mechanisms of pathophysiology associated with toxin threats and developing critical proteomics capability	vaccine candidates in established model systems for Ebola virus. Develop higher animal species models for eastern equine encephalitis virus.

3.5.2.6 Assessment of Medical Biological Defense Applied Research. Applied research efforts in FY2001for project TB2 are at least minimally effective. Many areas of medical biological defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that most DTOs in this area were rated green. One DTO was rated yellow and concerns were expressed about two additional DTOs. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2001.

3.5.3 Medical Chemical Defense Applied Research (Project TC2)

This project funds medical chemical defense applied research and emphasizes the prevention of chemical casualties through application of pharmaceuticals for prevention and treatment of the toxic effects f nerve, blister, respiratory, and blood agents. This project supports applied research of prophylaxes, pretreatments, antidotes, skin decontaminants, and therapeutic compounds that will counteract the lethal, physical, and behavioral toxicities of chemical agents. It also supports development of medical chemical defense materiel that ensures adequate patient care, field resuscitation, and patient management procedures. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas (Pretreatments, Therapeutics, and Diagnostics), and directed research efforts (Low Level Chemical Warfare Agent Exposure and Fourth Generation Agents).

3.5.3.1 TC2 Performance Goal (Outcome). The goal of medical chemical defense applied research is to increase scientific understanding of the mechanisms of action and effects of CW agents in order to demonstrate and develop technologies for preventive and therapeutic protection and diagnostics.

3.5.3.2 TC2 Outcome Measure

TC2 is minimally effective when	TC2 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – diagnostics, – low-level toxicology, – pre-treatments, – therapeutics, – novel threats, – optical recognition technologies, – new detection technologies. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA Panel.

3.5.3.3 Metric Description. The metric for TC2 is described in Section 3.2.1.1. Applied research also includes several specific projects that are identified as Defense Technology Objectives (DTOs), which are detailed and assessed separately (See section 3.3). DTOs funded under this project include:

- Chemical Agent Prophylaxes
- Medical Countermeasures against Vesicant Agents.

3.5.3.4 TC2 Actual and Planned Performance:

FY2001 Targets	Actual Performance
Diagnostics - Evaluate commercial off-the-shelf diagnostics for applicability as medical chemical defense.	*Diagnostics*: • Targets met.
Low Level - Determine pharmacological, physiological, and toxicological effects of long-term, low-level CW agents. Investigate new sensitive biochemical and histological assay technologies for use in low level CW agent exposures. Investigate the use of biological markers to indicate prior low-dose CW agent exposure.	*Low Level:* • Targets met.
Novel Threats (Fourth Generation Nerve Agents) - Assess the efficacy of countermeasures currently fielded, in advanced or exploratory development for efficacy against nerve agents.	*Novel Threats*: • Targets met.
Pretreatments - Extend molecular modeling and site-directed mutagenesis research to develop next generation nerve agent bioscavenger.	*Pretreatments*: • Targets met.
Therapeutics - Optimize formulations for sponges, towelettes, and surgical pads containing scavenger enzymes for use in wound decontamination.	*Therapeutics:* • Targets met. In addition, began efforts to acquire human butyrylcholinesterase enzyme in bulk. Screened midazolam plus candidate anticholinergic compounds for improvement in reducing/ eliminating nerve agent- induced seizures.

3.5.3.5 TC2 Future Targets

FY 2002 Targets	FY 2003 Targets
Diagnostics - Modify currently fielded cholinesterase testing kit to more efficiently test a large sample load.	*Diagnostics* - Pursue development of an acetylcholinesterase monitoring device that will allow

FY 2002 Targets	FY 2003 Targets
Pretreatments - Develop animal models to test scavenger candidates efficacy. Conduct characterization studies. Begin preliminary efficacy studies with next generation nerve agent scavengers. Continue development of potential transgenic/bioengineered sources of next generation nerve agent. *Therapeutics* - Assess candidate agents in suitable animal models of soman-induced status epilepticus for efficacy in saving vulnerable neurons and improving neurobehavioral outcome. Develop criteria for evaluating neuronal salvage after status epilepticus. Determine the essential ingredients for a rinse solution to optimally treat HD-induced ocular injury. Evaluate improved animal models for screening candidate combination therapies. *Low Level Chemical Warfare Agent Exposure* - Study biological markers for indicating prior low dose exposures and investigate selectivity of the markers for chemical warfare agents. *Fourth Generation Agents* - Assess the efficacy of new proposed nerve agent countermeasures. Prioritize potential approaches for improving effectiveness of new nerve agent countermeasures. Evaluate oxime effectiveness against Fourth Generation Agents. Evaluate newly identified anticonvulsants for improved survival after exposure to FGAs. Assess the effects of in vivo persistence of FGAs on current countermeasure efficacy. Confirm cardiac pathology seen after exposure to FGAs	real- time assessment of individual warfighter status/ exposure to nerve agents utilizing non- invasive measurement of endogenous enzyme levels. *Pretreatments* - Expand physiologically based pharmacokinetic models to include scavengers as a component in the presence and absence of chemical warfare agents. Utilize animal model(s) from which cyanide pretreatment/ treatment data can be extrapolated to humans. Initiate studies to evaluate potential pretreatments for mustard exposure using animal models. Investigate effectiveness of butyrylcholinesterase to prevent toxicity from exposure to low levels of CWA. *Therapeutics* - Evaluate new FDA- approved drugs for treatment of mustard- induced ocular injury. Optimize formulation for an ocular rinse that treats mustard-induced ocular injury. *Low Level Chemical Warfare Agent (CWA) Exposure* - Continue to study/ validate biological markers for low level CWA exposure in animal models. Investigate the effectiveness of selected pretreatment and treatment countermeasures for low level nerve agent exposure. Determine neurobehavioral deficits resulting from exposure to low levels of nerve agents. Investigate potential therapeutic use of HBuChE for low level nerve agent exposure.

3.5.3.6 Assessment of Medical Chemical Defense Applied Research. Applied research efforts in FY2001 for project TC2 are effective. Many areas of medical chemical defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that all DTOs in this area were rated green. Additionally, the successful assessment is based on the transition of two DTO efforts successfully transitioning to advanced technology development. These DTOs include Medical Countermeasures to Vesicant Agents and Medical Chemical Agent Prophylaxes. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2001.

3.6 ADVANCED TECHNOLOGY DEVELOPMENT (PROGRAM ELEMENT 0603384BP)

This program element demonstrates technologies that enhance the ability of U. S. forces to defend against, and survive CB warfare. This PE funds advanced technology development for Joint Service and Service- specific requirements in both medical and non- medical CB defense areas. The medical program aims to produce drugs, vaccines, and medical devices as counter-measures for CB threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical

management of casualties. In the non- medical area, the focus is on demonstrations of CB defense technologies, including biological detection, chemical detection, and decontamination. These demonstrations, conducted in an operational environment with active user and developer participation, integrate diverse technologies to improve DoD CBW defense and deterrence. These demonstrations are leveraged by the Counterproliferation Support Program and include remote Biological Detection. Work conducted under this PE transitions to and provides risk reduction for Demonstration/ Validation (PE 0603884BP) and Engineering/ Manufacturing Development (PE 0604384BP) activities. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. This PE also provides for the conduct of advanced technology development in the areas of real- time sensing, accelerated BW operational awareness, and the restoration of operations following a BW/ CW attack. This program is dedicated to conducting proof- of- principle field demonstrations, and tests of system-specific technologies to meet specific military needs.

3.6.1 Chemical and Biological Defense Advanced Technology Development (Project CB3)

This project demonstrates technology advancements for Joint Service application in the areas of chemical and biological agent detection and identification, decontamination, and individual/ collective protection which will speed maturing of advanced technologies to reduce risk in system- oriented Demonstration and Validation efforts. This project funds the Joint Service Fixed Site Decontamination (JSFXD) Program, the Joint Service Warning and Identification LIDAR (Light Detection And Ranging) Detector (JSWILD) Program,(JSWILD is transitioning to ARTEMIS in CP4, in FY01 and CA4, in FY02 and beyond.) the Joint Service Sensitive Equipment Decontamination (JSSED) Program, the Joint Chemical/ Biological Agent Water Monitor (JCBAWM), the Joint Biological Standoff Detection System (JBSDS), the Joint Service Wide Area Detector (JSWAD), and Joint Operational Effects Federation (JOEF). Additionally, this program funds the Small Unit Biological Detector (SUBD), Consequence Management Interoperability Service (CMIS), and the Chemical Biological Individual Sampler (CBIS).

3.6.1.1 CB3 Performance Goal (Outcome). The goal of the CB defense non-medical advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the detection, protection against, and decontamination of CBW agents.

3.6.1.2 CB3 Outcome Measure

CB3 is minimally effective when	CB3 is successful when
• The results provide fundamental information and demonstrate improved capabilities in support of new and improved defensive systems, including information and capabilities for: – Advanced materials for individual protection, – Detection of chemical and biological contamination, – Decontamination of sensitive equipment, – Early warning chemical and biological detection capabilities • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs rated GREEN by the TARA panel

3.6.1.3 Metric Description. The metric for CB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific projects that are identified as Defense Technology Objectives (DTOs), which are detailed and assessed separately (See section 3.3). DTOs funded under this project include the following:

- Force Medical Protection (CBIS) ACTD
- CB Agent Water Monitor
- CBW Effects on Operations
- Oxidative Decontamination Formulation
- Self-Detoxifying Materials for CB Protective Clothing.

3.6.1.4 CB3 Actual and Planned Performance:

FY2001 Targets	Actual Performance
JSSED - Conduct development of sensitive equipment/ items decontamination technologies (Block I) with emphasis on the advanced development of technologies for interior decontamination (block II/III). Support the Defense Systems Acquisition Management Program which provides acquisition and transition management for the JSSED program.	*JSSED*: • Targets met.
Detection Technologies - Evaluate and support accelerated efforts to meet entrance criteria of high potential technologies to address high priority CINC needs being planned in various ACTDs and upcoming mature programs. The effort will involve hyperspectral imaging, a test representative Radar system to provide cueing and early warning capabilities, and a hybrid LIDAR concept for a potential man-portable sized short range biological detection system which is similar to but more logistically/ maintainable in comparison to the CP SR-BSDS being evaluated in the JBREWS ACTD.	*Detection Technologies*: • Targets met. Other research activities included the following: *CB Advanced Materials Research* - Demonstrated the value of advanced material used in protection concepts for filtration, clothing, and tentage. *SUBD* - Advanced the current component technologies to a final configuration and paid for contract closeout and archiving of data. *CMIS* - Initiated development of a "common operating view" that enables DoD to view tactical information in advance of arriving at the scene of a WMD incident. Tailored COTS software that is adapted to the "lowest common denominator". Evaluated Geospatial Information System (GIS) data and applications for WMD incidents.

3.6.1.5 CB3 Future Targets

FY 2002 Targets	FY 2003 Targets
JSSED - Evaluate Block II/III technologies. Perform agent chamber/panel tests to validate performance of candidate technologies on a variety of surfaces. Address material compatibility issues. Initiate documentation of	*Joint Operational Effects Federation (JOEF)* - Conduct Analysis of Alternatives (AoA) and market survey. Establish Joint System Architecture IPT and Joint T& E IPT. Coordinate and create the Test and Evaluation

FY 2002 Targets	FY 2003 Targets
technology findings to support transition to development. *JSFXD Block III* - Conduct down selection screen of candidate skin decontamination identified in the FEA. Compare to baseline M-291 kit. Candidate technologies include the nanoemulsion system developed by the DARPA program and a foam system developed under the Department of Energy Chemical Biological National Security Program. Transition optimal candidate(s) to JSFXD Demonstration/Validation phase for insertion into the FDA approval process. *Foam Based Decontamination Systems* - Conduct evaluation of and modify the DOE foam based decontamination system to meet military challenge levels. Extend the test bed to include Fourth Generation Agents. *Detection Technologies* - Complete assessment of hyperspectral imaging technologies and establish transition points for the highest potential payoff capabilities. *Portable Chemical/Biological Detection Technologies* - Initiate evaluation of technologies from all sources for feasibility in application to military requirements for potentially man-portable multi-agent chemical and biological detectors with reduced logistics burden. The effort will focus on performance characterization and chamber test with identification of technological shortfalls. Specific initial candidates include DOE micro-CB lab, pyrolysis-GC/IMS, optical particle classifier. *Biological Detection Technologies* - Develop assays and initiate live agent testing of DARPA Micro Array of Gel-Immobilized Compounds (MAGIChip) nucleic acid identification technology for Bacillus species. Initiate automation of DARPA-developed ultraviolet-infrared matrix-assisted laser desorption (MALDI) mass spectrometry (MS). Initiate comparative evaluation for sensitivity and discrimination capability of UV-MALDI and UV-IR MALDI MS candidates from DARPA and electrospray ionization (ESI) MS using aerosol collections in chamber tests. Identify sample processing challenges for improvement *Joint Field Trials* - Expand the biological Joint Field Trial concept to a multi-tiered set of evaluation protocols to facilitate the characterization of candidate technology at varying levels of maturity.CB Modeling/Simulation - Accelerate development and demonstration of models describing impacts of CBW on site operations. *Technology Transition* - Conduct acceptance testing of anthrax antibody mixtures under development for improved affinity. Complete testing of upconverting phosphors. Implement improved sample treatment procedures for MALDI-TOF mass spectrometer and	Master Plan (TEMP). Develop the Acquisition Strategy and supporting acquisition documentation. Demonstrate the maturity of the JOEF Blk I Federate. Conduct Interoperability Assessment and a System Threat Assessment. *JSSED* - Complete the transition of JSSED Block II/ III technologies to demonstration and validation program. *Technology Readiness Evaluation Program* - Continue development and initiate implementation of expanded multi-tiered set of evaluation protocols to address all stages of chemical/ biological defense materiel development from system concept development to mature technology/ NDI/ COTS systems to facilitate fair evaluation of technology candidates from all sources. *Joint Service Wide Area Detector (JSWAD)* - Initiate planning for technology transition to System Development & Demonstration. Initiate design and build of brassboard system for demonstration. *Advanced Filtration* - Demonstrate fiber-immobilized carbon particles from DARPA project in mask filter designs (Joint Service General Purpose Mask (JSGPM), the Joint Service Aviator Mask (JSAM)), collective protection designs (JTCOPS (Joint Transportable Collective Protection Shelter) and production filters (Joint Collective Protection Equipment)). *Modeling and Simulation* - Complete and transition Joint Environmental Model to the Joint Warning and Reporting Network (JWARN). Complete and transition Simulation, Training and Analysis for Fixed Sites (STAFFS) to Joint Warfare System (JWARS). *Technology Transition* - Continue development of sample treatment procedures for MALDI-TOF mass spectrometer and demonstrate in a field evaluation. Continue development of assays and live agent testing of DARPA Micro Array of Gel-Immobilized Compounds (MAGIChip) nucleic acid identification technology for Bacillus species. Continue automation of DARPA-developed ultraviolet-infrared matrix-assisted laser desorption (MALDI) mass spectrometry (MS). Continue comparative evaluation and improve sensitivity and discrimination capability of UV-MALDI and UV-IR MALDI MS candidates from DARPA and electrospray ionization (ESI) MS. Initiate the militarization of DOE's microlab technology, Handheld Advanced Nucleic Acid Analyzer (HANAA), and decontamination foam system. Continue development and testing of thermocatalytic air purifier technology for collective protection shelters, focus is on a DARPA technology in thin-foil high efficiency heat-exchanger and system design.

FY 2002 Targets	FY 2003 Targets
prepare for field evaluation	

3.6.1.6 Assessment of Chemical and Biological Defense Advanced Technology Development. Advanced Technology Development efforts in FY2001 for project CB3 were effective. Many areas of CB defense advanced technology development were successful. The assessment for success is based on the assessment of the TARA panel that all DTOs in this area were rated green. Extensive development continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2001.

3.6.2 Counterproliferation Support Advanced Technology Development (Project CP3)

The mission of the Counterproliferation Program (CP) is to address shortfalls in the DoD deployed capability to defend against and counter the proliferation of WMD. By focusing on near term results, the CP accelerates delivery of new tools, equipment, and procedures to combat forces. Under the passive defense pillar, CP enhances the efforts of the Chemical and Biological Defense Program. This project funds a variety o f programs to defend our forces against WMD, such as the Biological Detection (BIODET), Biological Non-Systems (BIO Non Sys) efforts, Critical Reagents Program (CRP), Restoration of Operations (RESTOPS) and a Planning and Development for Advanced Concept Technology Demonstrations (ACTD- PD).

3.6.2.1 CP3 Performance Goal (Outcome). The goal of the counterproliferation support advanced technology development program is to demonstrate advanced capabilities and concepts involved in the detection, protection against, and decontamination of CBW agents.

3.6.2.2 CP3 Outcome Measure

CP3 is minimally effective when	CP3 is successful when
• The results provide fundamental information and demonstrate improved capabilities in support of new and improved defensive systems, including information and capabilities for: – Biological detection systems. – Critical reagents for biological detection and identification. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA

3.6.2.3 Metric Description. The metric for CP3 is described in Section 3.2.1.1. Advanced technology development also includes several specific projects that are identified as Defense Technology Objectives (DTOs), which are detailed and assessed separately (See section 3.3). DTOs funded under this project includes the Restoration of Operations (RestOps) ACTD.

3.6.2.4 CP3 Actual and Planned Performance:

FY2001 Targets	Actual Performance
BIODET - Produce nucleic acid primer libraries for testing and continue development of a biological detection capability using nucleic acids.	*BIODET*: • Targets met. In addition, completed the transition to project CB3 for test, evaluation, and

FY2001 Targets	Actual Performance
	further assay development against live agents under tech transfer funds.
<u>CRP</u> - Continue to develop reagents (antibodies and antigens) that are critical to the development, testing, and support of CP Biological Detection Systems.	<u>CRP</u>: • Targets met.
<u>BIO Non Sys</u> - Continue development and evaluation of generic detectors (UV) and associated algorithms to provide increased warning time for tactical battlefield applications. Continue development, testing, and evaluation of automated sample preparation technology and protocols for Polymerase Chain Reaction (PCR) devices to improve identification specificity and sensitivity in future biological systems	*BIO Non Sys* • Targets met. In addition, completed transition of TOF MS/ MS to CB3 program. Initiated synthetic environment tool for technology selection for RestOps scenarios. Initiated testing of warfare agents on RestOps scenario surfaces for use in modeling and simulation. Other research activities included ACTD planning and development: <u>ACTD-PD</u> - Performed technology maturity evaluations for selection of technologies for Integrated Chemical Biological ACTD. Initiated maturation of Standoff Detector for use as a surface chemical detector.

3.6.2.5 CP3 Future Targets

FY 2002 Targets	FY 2003 Targets
<u>ACTD-PD</u> - Perform technology maturity evaluations, perform analysis of alternative technologies, and prepare acquisition strategy for Contamination Avoidance for Seaports of Debarkation (CASPOD) Advanced Concept Technology Demonstration. <u>BIO Non Sys</u> - Initiate development and testing of improved UV detectors, UV micro-lasers, and algorithms. Initiate prototype development and testing of an optical based detector using high affinity nucleic acid aptamer chips. Initiate challenges to detector systems in development using Red Teams. Initiate development and testing of a new improved collector/concentrator and pre-separator devices for filtering and cleaning environment air samples. <u>BIO Non Sys</u> - Continue development and evaluation of generic detectors (TOF MS/MS, UV) and associated algorithms to provide increased warning time for tactical battlefield applications. Continue development, testing, and evaluation of automated sample preparation technology and protocols for PCR devices to improve identification specificity and sensitivity in future biological systems. <u>BIO Non Sys</u> - Develop decontaminants, equipment, procedures, techniques, and tactics for decontamination of wide body and other aircraft	<u>ACTD- PD -</u> Perform technology maturity evaluations for selection of technologies for future ACTD candidate. <u>BIO Non Sys -</u> Initiate short term projects resulting from Department of Defense collaboration efforts with non-DoD agencies to accelerate promising technologies that can fill technology gaps in the DoD CBDP. <u>BIO Non Sys -</u> Continue development and demonstration of improved Hand Held Assay (HHA) device for fielded bio detection systems, including legacy systems in an attempt to improve the three basic aspects of the HHA: reagents, format and solid phase. Initiate development of Biological Attribution technology to capture a suite of leading edge biotechnology techniques by which any sample of biological material could be analyzed to detect a specific signature that will lead to a determination of its origin.

3.6.2.6 Assessment of Counterproliferation Support Advanced Technology Development. Advanced Technology Development efforts in FY2001 for project CP3 were somewhat successful. Upconverting Phosphors (UCP) technology migrated from DARPA to JPO-BD in an attempt to use in hand held assays. The original medium for demonstrating UCP technology, flow cytometer, was intended for JBPDS, yet flow cytometry was removed from the block upgrade plan for JBPDS. The flow cytometer could be useful in a Theatre Army Medical Lab like system, however CP funding will no longer be applied in this area. The Time of Flight Mass Spectrometer was evaluated by JPO-BD in a Joint Field Trial. The TOF MS was lacking a trigger and needs substantially more engineering development. No further CP funding is intended for this effort. The effort was moved back to the tech base program.

3.6.3 Medical Biological Defense Advanced Technology Development (Project TB3)

This project funds preclinical development of safe and effective prophylaxes and therapies (vaccines and drugs) for pre- and post- exposures to biological threat agents. This project also supports the advance d technology development of diagnostic devices to rapidly diagnose exposure to biological agents in clinical samples. A broad range of technologies involved in the targeting and delivery of prophylactic and therapeutic medical countermeasures and diagnostic systems is evaluated so that the most effective countermeasures are identified for transition to Advanced Development. Transitioning candidate vaccines, therapeutics, and diagnostic technologies to Advanced Development requires the development of scientific/ regulatory technical data packages to support the Food and Drug Administration (FDA) Investigational New Drug (IND) process and DoD acquisition regulations. Categories for this project include Defense Technology Objectives (DTOs); science and technology program areas in medical biological defense (diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines), directed research efforts (Bioadhesion Research, Medical Chemical/ Biological Counterterrorism Support, Medical Countermeasures, Advanced Diagnostics, and Vaccines); and efforts to transition promising medical biological defense technologies from DARPA.

3.6.3.1 TB3 Performance Goal (Outcome). The goal of the medical biological defense advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the preventive and therapeutic countermeasures and diagnostics for BW agents.

3.6.3.2 TB3 Outcome Measure

TB3 is minimally effective when	TB3 is successful when
• The results provide fundamental information and demonstrates advanced capabilities in support of new and improved defensive systems, including: – Bacterial Therapeutics, – Toxin Vaccines, – Bacterial Vaccines, – Toxin Therapeutics, – Viral Therapeutics, – Viral Vaccines, – Diagnostic Technologies, and	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA

TB3 is minimally effective when	TB3 is successful when
– Protocols to Enhance Biological Defense. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	

3.6.3.3 Metric Description. The metric for TB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific projects that are identified as Defense Technology Objectives (DTOs), which are detailed and assessed separately (See section 3.3). DTOs funded under this project include the following:

- Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases.
- Medical Countermeasures for Encephalitis Viruses
- Multiagent Vaccines for Biological Threat Agents
- Medical Countermeasures for Brucellae
- Alternate (Needleless) Delivery Methods for Recombinant Staphylococcal Enterotoxin Vaccines
- Recombinant Protective Antigen (rPA) Anthrax Vaccine Candidate
- Recombinant Plague Vaccine.

3.6.3.4 TB3 Actual and Planned Performance:

FY2001 Targets	Actual Performance
Bacterial Therapeutics - Test selected immunomodulators in appropriate animal models for protection against plague and glanders.	*Bacterial Therapeutics*: • Targets met.
Bacterial Vaccines - Explore laboratory formulations of candidate glanders, plague, and anthrax vaccines using various adjuvants to enhance immunogenicity.	*Bacterial Vaccines*: • Targets met.
Toxin Therapeutics - Begin stability testing of the recombinant ricin A-chain that is being used for enzymatic activity studies.	*Toxin Therapeutics*: • Targets met.
Toxin Vaccines - Complete the process development (60 L scale-up) for vaccine botulinum toxin serotypes C1 and E in the Pichia yeast system and complete efficacy studies. Initiate formulation studies on a combinatorial recombinant pentavalent botulinum toxin vaccine. Develop reagents and assays to determine quality and quantity of botulinum toxin, SE, and ricin vaccines during process development. Initiate preparation of technical data package in support of IND submission to the FDA for SE vaccine candidate.	*Toxin Vaccines*: • Targets met.
Viral Therapeutics - Determine dose and schedule for lead antiviral drug candidate for intravenous treatment of smallpox. Develop formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox and filoviruses.	*Viral Therapeutics*: • Targets met.
Viral Vaccines - Test prime-boost vaccine candidates for Ebola virus in nonhuman primate models. Test VEE replicon-based vaccines packaged in different glycoproteins for immunogenicity	*Viral Vaccines*: • Some targets met. Did not complete replicon-based vaccine testing.

FY2001 Targets	Actual Performance
and protection against Ebola virus. *Diagnostic Technologies* - Compare alternative medical diagnostic technologies and specimen processing methods compatible with a comprehensive integrated medical diagnostic system for the rapid recognition of infections by validated biological threats (bacteria, viruses, and toxins) in laboratory-based and field-based studies. Exploit promising technologies transitioned from DARPA.	*Diagnostic Technologies*: • Targets met. DARPA technologies evaluated included novel molecular methods for selecting vaccine antigens, novel antibacterial agents, and plant-based expression of antibodies. Additional research activities include the following: *Bioadhesion Research* - Continued research evaluating the mechanisms that block the adhesion of pathogens, whether microbes or toxins, to host cells thereby preventing initiation of the disease/ intoxication process. The research was aimed toward the development of medical countermeasures for two BW threats (Bacillus anthracis and Brucellae sp.) and an infectious disease (ID) agent (Norwalk virus). *Medical CB Counterterrorism Support* - Continued research on the development of technologies to identify chemical and biological warfare agents (CBWA), laboratory procedures specific for the medical diagnosis or identification of CBWA exposure, information relevant to the collection of biological samples (blood, urine, or skin biopsy), and basic training in assay use and transition. Developed assays for use by the newly constituted National Guard Mobile Analytical Laboratory System (NGMALS).

3.6.3.5 TB3 Future Targets

FY 2002 Targets	FY 2003 Targets
Diagnostic Technologies - Compare new diagnostic reagents, devices, and protocols in preclinical studies before transition to the regulatory-compliant medical laboratory. Evaluate candidate diagnostic technologies in field-based studies and in a highly regulated medical center clinical laboratory prior to transitioning to Demonstration and Validation. *Bacterial Therapeutics* - Evaluate in animal models selected immunomodulators in combination with efficacious antibiotics for protection against bacterial threat agents. *Toxin Therapeutics* - Optimize formulation and pharmacodynamics of lead candidate licensed drugs that also inhibit SE-induced intoxication. *Viral Therapeutics* - Continue evaluating formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox and	*Diagnostic Technologies* - Compare alternative diagnostic technologies for the rapid identification of biological threat agents in laboratory-based and field-based studies prior to transition to the field medical laboratory. Compare overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of detecting and identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies. *Bacterial Therapeutics* - Conduct advanced comparative assessment of immunomodulators and other types of broad-spectrum compounds for safety and efficacy against multiple biological threat agents. *Toxin Therapeutics* - Prepare sufficient amounts of lead inhibitors of botulinum and SEB intoxication for testing in vivo. *Viral Therapeutics* - Evaluate the combined approach of antiviral drug therapy and immunotherapy in treatment

FY 2002 Targets	FY 2003 Targets
filoviruses. *Bacterial Vaccines* - Validate correlates of immunity for protection against B. anthracis; evaluate vaccine candidates and correlates of immunity for B. mallei. *Toxin Vaccines* - Complete formulation studies on a combinatorial recombinant pentavalent botulinum toxin vaccine. Initiate formulation studies on a combinatorial SE vaccine. Complete development of reagents and assays to determine the quality and quantity of recombinant botulinum and SE vaccines during process development. Initiate the process development (60 L scale-up) for botulinum toxin serotypes D and G in the Pichia yeast system and complete efficacy studies. Initiate the process development for SE serotype A and complete efficacy studies. Initiate in vivo concept model systems for assessment of vaccine efficacy and surrogate endpoints of human clinical efficacy for botulinum toxin and SE intoxication. *Viral Vaccines* - Determine optimal dose and schedule for vaccination against MBGV. Demonstrate in pivotal animal studies that the vaccine candidate is efficacious against aerosol infection with MBGV. *DARPA Program Transition* - Expand DARPA transition efforts to include novel molecular method for selecting vaccine antigens, additional antiviral agents, and evaluation of plant-based antibodies as therapeutic agents. *Vaccines* - Enhance advanced technology development efforts toward innovative approaches for the development and delivery of next generation and generation-after-next vaccines and strategies to enhance the immune response to broad classes of biological threats. *Medical Countermeasures* - Enhance advanced technology development efforts toward the development of broad-spectrum therapeutic countermeasures for exposure to broad classes of biological threats. *Advanced Diagnostics* - Enhance advanced technology development efforts toward the development of advanced medical diagnostic capabilities.	of disease from filoviruses. Continue evaluating formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox and filoviruses. *Bacterial Vaccines* - Compare most efficacious and safe vaccine candidates against selected agent exposures. Complete studies required to prepare a technical data package supporting transition of the best vaccine candidates to advanced development. *Toxin Vaccines* - Complete process development (60 L scale-up) for botulinum toxin serotypes D and G in the Pichia yeast system. Complete efficacy studies on recombinant ricin toxin A-chain (rRTA) vaccine candidates and downselect best rRTA vaccine candidate. *Viral Vaccines* - Determine and test the optimal vaccine strategy to protect against Ebola virus. Complete the development of vaccine candidates for WEE virus. *DARPA Program Transition* - Continue expansion and definition of medical biological defense technologies transitioned from the DARPA. Characterize and perform process development on candidate vaccines and therapeutics deemed sufficiently mature for transitioning to advanced development.

3.6.3.6 Assessment of Medical Biological Defense Advanced Technology Development. Advanced technology development efforts in FY2001 for project TB3 are effective. Many areas of medical biological defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that all DTOs in this area were rated green. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2001.

3.6.4 Medical Chemical Defense Advanced Technology Development (Project TC3)

This project supports the investigation of new medical countermeasures to include antidotes, pretreatment drugs, and topical skin protectants to protect U. S. forces against known and emerging CW threat agents. Capabilities are maintained for reformulation, formulation, and scale- up of candidate compounds using current good laboratory practices. Analytical stability studies, safety and efficacy screening, and preclinical toxicology studies are performed prior to full- scale development of promising pretreatment or treatment compounds. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas (Pretreatments, Therapeutics, and Diagnostics), and directed research efforts (Low Level Chemical Agent Exposure and Fourth Generation Agents).

3.6.4.1 TC3 Performance Goal (Outcome). The goal of the medical chemical defense advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the preventive and therapeutic countermeasures and diagnostics for CW agents.

3.6.4.2 TC3 Outcome Measure

TC3 is minimally effective when	TC3 is successful when
• The results provide fundamental information and demonstrate advanced capabilities in support of new and improved defensive systems, including information on – chemical agent therapeutics, – chemical agent prophylaxes, – chemical agent diagnostics, – novel threat agents, – low level operational toxicology. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA.

3.6.4.3 Metric Description. The metric for TB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific projects that are identified as Defense Technology Objectives (DTOs), which are detailed and assessed separately (See section 3.3). DTOs funded under this project include the following:

- Chemical Agent Prophylaxes
- Active Topical Skin Protectant
- Medical Countermeasures for Vesicant Agents

3.6.4.4 TC3 Actual and Planned Performance:

FY2001 Targets	Actual Performance
Diagnostics - Evaluate modified advanced development equipment or technologies for far-forward screening and confirmation of exposure to blister and nerve agents; conduct surveys of existing commercial technologies and	*Diagnostics*: • Most targets met. Did not develop MALDI-TOF MS to measure HD.

FY2001 Targets	Actual Performance
test suitability of these items. Develop a matrix-assisted laser desorption ionization time-of-flight mass spectrometry method to measure HD in the warfighter.	
<u>*Novel Threats*</u> - Select best countermeasures to novel threats based on comparison of protection against lethality, pathology, physiological dysfunction, and behavioral incapacitation.	<u>*Novel Threats*</u>: • Targets met.
<u>*Pretreatments*</u> - Conduct safety and efficacy studies of bioscavenger candidates.	<u>*Pretreatments*</u>: • Targets met. Bioscavengers tested in two animal models. In addition, determined 3D x- ray crystallographic structure of human carboxylesterase and paraoxonase- 1.
<u>*Therapeutics*</u> - Evaluate the efficacy of lead vesicant countermeasure compounds identified in earlier screening efforts using a drug decision approach (decision tree network). Begin vesicant candidate safety and efficacy studies in two animal models. Evaluate the optimal treatment strategy for mustard-induced ocular injury using steroid/antibiotic combinations. Evaluate commercially available off-the-shelf wound healing products to treat HD-induced injuries.	<u>*Therapeutics*</u>: • Targets met. In addition, determined lead anticholinergic drugs for use with midazolam as therapy for nerve agent exposure.

TC3 Future Targets

FY 2002 Targets	FY 2003 Targets
<u>*Diagnostics*</u> - Test a prototype noninvasive monitor that measures oxyhemoglobin, deoxyhemoglobin, methemoglobin, and carboxyhemoglobin via finger, ear, or toe.	<u>*Diagnostics*</u> - Evaluate hand- held cholinesterase (ChE) monitor for hospital use. Validate immobilized cholinesterases and nerve agent hydrolyzing enzymes as diagnostics for nerve agent exposure. Evaluate commercially available off- the- shelf wound healing products for mustard- induced injuries. Evaluate therapeutic agents for pulmonary edema produced by whole- body exposure to CWAs.
<u>*Pretreatments*</u> - Complete development/validation of a transgenic animal model capable of producing sufficient amounts of recombinant enzyme scavenger material for clinical trials. Produce nerve agent scavengers in transgenic models and test for safety and efficacy in two animal species. Complete physiologically based pharmacokinetic model studies of expected human efficacy with various scavengers to assist in an IPR downselect process.	<u>*Pretreatments*</u> - Complete physiologically based pharmacokinetic model studies of expected human efficacy with various catalytic scavengers. Verify adequacy of transgenic animal model to produce recombinant catalytic enzyme scavenger.
<u>*Therapeutics*</u> - Determine optimal combination of midazolam and anticholinergic drug and order of administration to obtain maximal anticonvulsant effect against seizures in a nonhuman primate model. Conduct studies directed at obtaining FDA approval for an ocular rinse that optimally treats mustard-induced injuries. Select combination therapy approaches that provide highest level of protection in animal models for safety and efficacy advanced screening. Conduct pharmacokinetics and formulation studies of vesicant countermeasure candidates. Study efficacy and safety of vesicant countermeasure candidates. Determine window of opportunity for administration of therapy(s) for blister agent HD exposure	<u>*Therapeutics*</u> - Select optimal anticholinergic drug for inclusion with midazolam and establish optimal suggested treatment protocol in higher animal species. Complete preclinical studies of selected vesicant therapy candidate compounds.
<u>*Fourth Generation Agents*</u> - Begin downselect process of best available countermeasure(s) against Fourth	<u>*Fourth Generation Agents (FGAs)*</u> - Perform advanced assessment of medical countermeasures in guinea pigs by evaluation of physiological and histopathological parameters. Evaluate bioscavenger pretreatment as medical countermeasure against FGAs in guinea pigs. Conduct advanced assessment (pharmacokinetic and bioavailability) studies of lead medical countermeasures to FGAs in higher animal species for human efficacy estimation.

FY 2002 Targets	FY 2003 Targets
Generation Agents. Initiate formulation and bulk production feasibility efforts	Develop surrogate markers in guinea pigs for alternative medical countermeasures for FGA exposure. Develop downselection criteria for choice of the best of the candidates for improved medical countermeasures to FGA exposure.

3.6.4.5 Assessment of Medical Chemical Defense Advanced Technology Development. Advanced technology development efforts in FY2001 for project TC3 are effective. Many areas of medical chemical defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that all DTOs in this area were rated green. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2001.

Appendix 1
FY2002 Chemical/Biological Defense Defense Technology Objectives (DTOs)

This appendix provides a summary description of the objectives, payoffs, and challenges of the supporting chemical and biological defense. DTOs represent high priority efforts with the various business areas of the Chemical and Biological Defense Program. Table 1 provides a complete listing of all current DTOs and the corresponding reference number.

Table 1. Chemical and Biological Defense DTOs

DTO No.	DTO Title
I.03	Restoration of Operations ACTD.
I.04	Contamination Avoidance at Seaports of Debarkation ACTD
CB.08	Advanced Adsorbents for Protection Applications
CB.09	Enzymatic Decontamination
CB.19	Chemical Imaging Sensor
CB.20	Biological Sample Preparation System for Biological Identification
CB.24	Medical Countermeasures for Encephalitis Viruses
CB.25	Multiagent Vaccines for Biological Threat Agents
CB.26	Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases
CB.27	Therapeutics Based on Common Mechanisms of Pathogenesis
CB.28	Chemical Agent Prophylaxes II
CB.29	Active Topical Skin Protectant
CB.30	Medical Countermeasures for Vesicant Agents II
CB.31	Medical Countermeasures for Brucellae
CB.32	Needle-less Delivery Methods for Recombinant Protein Vaccines
CB.33	Recombinant Protective Antigen Anthrax Vaccine Candidate
CB.34	Recombinant Plague Vaccine
CB.35	Standoff Biological Aerosol Detection
CB.36	Universal End-of-Service-Life Indicator for NBC Mask Filters
CB.37	CB Agent Water Monitor
CB.38	Activity-Based Detection and Diagnostics
CB.39	CW/BW Agent Screening and Analysis
CB.40	Immune Building Program
CB.41	Biological Warfare Defense Sensor Program
CB.42	Environmental Fate of Agents
CB.43	Chemical and Biological Warfare Effects on Operations
CB.44	Oxidative Decontamination Formulation
CB.45	Self-Detoxifying Materials for Chemical/Biological Protective Clothing
BE.10	High-Resolution Meteorological Nowcasting for Chemical/Biological Hazard Prediction
L.07	Terrorist Chemical/Biological Countermeasures
L.12	Force Medical Protection/Dosimeter ACTD

I.03 Restoration of Operations ACTD.

Objectives. Demonstrate those mitigating actions taken before, during, and after an attack to protect against and immediately react to the consequences of a CB attack. These actions aim to restore operating tempo (OPTEMPO) in mission execution and the movement of individuals and materiel to support combat operations at a fixed site.

Payoffs. Potential payoffs include an improved understanding of the effectiveness of CB technologies, coupled with improved Concept of Operations (CONOPS), for fixed site CB defense operations. The ultimate payoff will be the improved ability of fixed sites worldwide to better prepare for and recover from CB attacks.

Challenges. The primary challenge is the development of the assessment plan and tools to accurately measure the effectiveness of the functions of a fixed site and their interdependencies in accomplishing the fixed-site mission in a CB environment. Technical challenges include the effective integration of situational awareness tools with CB sensors and then with the USAF Wing's command and control system.

I.04 Contamination Avoidance at Seaports of Debarkation ACTD.

Objectives. Identify the before, during, and after attack actions necessary to minimize the effects of a CB attack on force flow and operating tempo in support of contingency operations or theater war. The Contamination Avoidance at Seaports of Debarkation (CASPOD) ACTD focuses on chemical and biological (CB) defense at outside of CONUS seaports and the early and more vulnerable stages of power projection operations at sea ports in theaters where there is limited U.S. presence.

Payoffs. Potential payoffs includes providing the in-theater ability to protect against, immediately react to, and minimize the impact of a CB attack at seaports, thereby maintaining the critical flow of forces and materiel into any theater worldwide.

Challenges. Many of the emerging technologies being identified as candidates for the CASPOD ACTD will be leveraged from both the Seaport Protection Analysis (SPPA) program and the Restoration of Operation (RestOps) ACTD and are expected to be mature by FY03 when CASPOD exercises are being planned and executed. The greatest technical risk will be integrating these technologies so that they perform synergistically while configured as a "deployable package" to maintain or return a seaport of debarkation to near-normal levels immediately following a CB attack. An additional risk will be the identification and training of appropriate personnel (organized and trained for CB defense operations and available for deployment during an overseas contingency) to operate the equipment provided in the "flyaway" or transportable equipment package.

CB.08 Advanced Adsorbents for Protection Applications.

Objectives. Develop advanced adsorbent bed materials and compositions (e.g., layered adsorbents) to enhance the chemical agent and toxic industrial materials (TIMs) air filtration protection capabilities of current single-pass filters and regenerative filtration systems under development; and reduce the size, weight, encumbrance, and cost of existing filtration systems.

Payoffs. This DTO addresses JSIG JFOCs in individual and collective protection. Advanced adsorbent bed compositions for use in nuclear/biological/chemical (NBC) filters will result in smaller, lighter-weight filtration systems with reduced logistical requirements, improved protection against toxic industrial materials, and reduced combustibility. In FY00, families of adsorbents with proper characteristics for retention of low- to high-volatility chemicals (including uptake of ambient water) were identified. Adsorbent characteristics that affect chemical capacity and rate of desorption during purge were documented. In FY01, non-carbonaceous porous materials were found to provide enhanced filtration performance. About 200 novel adsorbents were evaluated for ability to sorb toxic industrial chemicals.

Challenges. For single-pass filters, adsorbent beds that improve kinetics of agent removal are needed to meet the goal of smaller, lighter-weight filters; also, specific impregnant formulations are needed owing to the diversity of the TIMs. The expanding number of TIMs requires novel technologies to provide the broad reactivity needed. An important challenge to address respirator filter needs for low breathing resistance is to identify adsorbent structures that exhibit reduced airflow resistance. For regenerable filters, adsorbent beds that readily release adsorbed agent during the purge cycle are needed to minimize size and energy requirements. The identification of noncombustible adsorbents with high levels of agent removal at all humidity conditions has proven to be an especially difficult challenge. Adsorbent bed compositions need to address recent approved requirements for NBC protection systems (e.g., Joint Service General Purpose Mask (JSGPM)), including capability for protection against TIMs, which is not adequately provided by current NBC filters.

CB.09 Enzymatic Decontamination.

Objectives. Develop and demonstrate a new generation of enzyme-based decontaminants that are nontoxic, noncorrosive, environmentally safe, and lightweight (freeze-dried concentrate).

Payoffs. This DTO addresses JSIG JFOC Restoration Capability: Equipment/Facilities/Large Area. Enzyme-based systems have the potential to reduce the logistical burden by 25- to 50-fold. High-activity G-agent enzymes have been identified, characterized, and demonstrated to be effective in NATO-sponsored agent trials. Several V-agent enzymes and H-agent reactive polymers have been identified, but their activity will need to be improved in order to reduce the quantities required. Enzyme-based materials may also have applications in some nonaqueous systems (sorbent, sensitive equipment decontamination) as well as personnel and casualty decontamination. Enzyme-based CW decontaminants can be mixed with a variety of naturally occurring and other mild biocidal materials to deal with BW agents as well. In FY99, enzymes for V- and H-agents were evaluated. Reactive polymers and other materials for enhanced H-agent hydrolysis/oxidation and compatibility with nerve agent enzymes were also evaluated. In FY00, enzyme activity against VX was increased 11-fold by site-directed mutagenesis and several new enzymes with V-agent activity identified. The production levels of recombinant G- and V-agent enzymes were increased significantly (3- to 5-fold). In FY01, formulations of V-agent enzymes and H-agent reactive materials were optimized for application in dispersion systems such as foams, detergent solutions, microemulsions, or other types of dispersion systems; new V-agent enzymes were identified; and the activity of enzymes was increased with hydrolytic activity on V-agents.

Challenges. The major technical challenge is to identify appropriate enzymes and enzyme-compatible chemicals that are (1) reactive with all nerve and blister agents; (2) genetically engineered for large-scale production; and (3) nontoxic, noncorrosive, and environmentally safe.

CB.19 Chemical Imaging Sensor.

Objectives. Demonstrate a lightweight, wide-area, passive standoff imaging detection system capable of rapidly detecting chemical agent vapors for the purpose of contamination avoidance, reconnaissance, and facilities evaluation. The final system will operate at 360 Hz with a 256 x 256 focal plane array (FPA), and is scheduled for transition to development in FY03. This DTO will focus on development of ultra-high-speed interferometers, integration of off-the-shelf FPAs, and development of a signal processing algorithm.

Payoffs. This DTO addresses JSIG JFOC Contamination Avoidance: Chemical Early Warning. The chemical imaging sensor (CIS) will allow rapid evaluation of large areas for chemical warfare (CW) contamination, and provide detailed information as to the position of a CW agent cloud. Current single-pixel designs have an extremely limited field of view (typically 26 m at a distance of 1 km). In addition, they cannot scan at sufficient speeds for proposed high-speed applications (i.e., tactical helicopter, high-speed aircraft, and hemispherical scanning applications). The CIS will be capable of operating at fields of view at least 250 times greater than current systems. In addition, scan speeds will be increased by almost two orders of magnitude for extremely high-speed applications. The potential deployments include fixed sites, ground vehicles, unmanned aerial vehicles, helicopters, high and low aircraft, and even low-Earth-orbit configurations. In FY99, real-time operation at 30 Hz was demonstrated. In FY00, a 16-pixel spectrometer at 100 Hz with offline data processing was demonstrated. In FY01, a 16-pixel spectrometer was demonstrated at 100 scans/sec with real-time signal processing.

Challenges. Proposed deployment of the CIS includes many ground and airborne scenarios that require high-speed operation. Speeds of at least 360 scans per second are required in many airborne operations in order not to "blur" the data. A significant effort is required to run an imaging spectrometer at these high speeds. The proposed spectrometer will contain (at the least) a low-density array of 9 to 16 pixels with higher density arrays being incorporated as they become available. The most significant current challenges are signal processing hardware and software, high-density FPA development, and high-speed interferometry. Commercially available interferometers typically operate at a few scans per second, with ten being a typical number. A CIS operating at 360 Hz with a 256 x 256 FPA will require about 1 TFLOP of computing power. Extrapolating current speed increases of high-speed computers into future signal processing hardware that can handle the CIS is expected to be available commercially in about 5 years.

CB.20 Biological Sample Preparation System for Biological Identification.

Objectives. Develop and demonstrate technology to reduce logistic burden associated with biological identification through an advanced, automated Biological Sample Preparation System (BSPS) for incorporation with genetic detection and identification systems. This DTO is extended to better address the primary objective to reduce the logistical burden that is only partially handled by an automated sample preparation system. The extended work will focus on the reduction of the total number of required assays through multiplexing/multi-agent analysis within a single sample.

Payoffs. When this DTO is completed, the technology will expand the scope of detectable and identifiable biological agents, shorten the time required for sample analysis, ensure that a maximum and properly prepared sample load is analyzed, and reduce the associated logistics burden as well as overall footprint associated with these detection technologies. In FY99, methodologies to reduce time for disruption of spores and viral particles to 20 min at sensitivities corresponding to one agent-containing particle per liter air, as measured using DNA detection on gene probe sensors and protein biomarkers in mass spectrometry, were demonstrated. In FY00, construction of automated concept BSPS systems was initiated, with testing scheduled for Joint Field Trial-6 (JFT-6) in Mar 2001. In FY01, the BSPS semi-automated systems were evaluated. The evaluated level of technological maturity in both systems showed that it was pre-mature in the consideration for the incorporation of microscale approaches to attempt further miniaturization. The mass spectrometry version was evaluated as pre-mature for the JFT-6 environment due to optimization and fluidic handling issues and further behind in maturity in comparison to the gene probe system. The gene probe version was demonstrated in semi-automated mode with shortened response time and reduction in the need for the man-in-the-loop, but not with significant reduction in reliance upon consumables.

Challenges. Major technical challenges include the removal of environmental/biological materials that may diminish performance of these platforms, rapid preconcentration of samples, rapid and efficient extraction of nucleic materials, automation of the entire sample treatment process to permit fully unattended operation, and the development of new chemistry to reduce the total number of assays needed through multiplexing/multi-agent (M/M) concepts for a single sample analysis.

CB.24 Medical Countermeasures for Encephalitis Viruses.

Objectives. Develop medical countermeasures against the biological warfare (BW) threat of theVenezuelan equine encephalitis (VEE) viruses (referred to as alphaviruses). Recombinant vaccine technology will be exploited to provide effective vaccine candidates.

Payoffs. The VEE group of viruses can cause flu-like symptoms, disorientation, convulsions, paralysis, and death. These viruses are normally transmitted to birds, horses, and humans by mosquito vectors, but are important BW threats because they are very stable when freeze-dried and highly infectious when transmitted by aerosol. There are currently no FDA licensed vaccines for protection from VEE viruses and current investigational vaccines are inadequate because they do not provide protection across the full spectrum of VEE strains, and have adverse effects. Improved vaccines will decrease the threat of BW and enhance strategic mobility. Under this DTO, vaccine components necessary to protect against genetically divergent VEE viruses will be constructed and evaluated.

Challenges. Major technical challenges include development of appropriate animal model systems for investigational purposes, and determining expression vectors for recombinant products.

CB.25 Multiagent Vaccines for Biological Threat Agents.

Objectives. Produce a vaccine or vaccine delivery approach that could be used to concurrently immunize an individual against a range of biological warfare (BW) threats. Bioengineered and recombinant vaccine technologies (naked DNA vaccines or replicon vaccines) will be exploited to achieve multivalent vaccines that are directed against multiple agents, yet use the same basic construct for all of the agents.

Payoffs. Vaccines currently being developed for biological threat agents are univalent with respect to the threat itself (e.g., separate vaccines against agents such as anthrax, plague, botulinum toxins, and smallpox). Multiagent vaccine technologies to be demonstrated through this DTO would be analogous to commercial vaccines, such as the combined diphtheria-pertussis-tetanus vaccine and the measles-mumps-rubella vaccine. The possibility of achieving protective immunity against multiple BW threat agents with a reduced requirement for the number of vaccines or immunization schedules means greater flexibility and fewer time constraints in fielding a protected force. Another potential benefit is the possibility of decreased cost of vaccine production. Due to the nature of some threat agents and lack of commercial viability for such a combined product, there are no other commercial or foreign sources by which to procure such products.

Challenges. Major technical challenges include scale-up production issues for the Venezuelan equine encephalitis (VEE) replicon platform, VEE replicon vaccine efficacy in light of pre-existing VEE immunity, enhancing the immunogenicity of DNA vaccines, driving different protective immune responses (i.e., TH1 *vs*. TH2) with a single vaccine platform, development of appropriate model systems for investigational purposes, and evaluation of immunogenicity, efficacy, and possible interference effects of the combined vaccine components in a multiagent vaccine candidate.

CB.26 Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases.

Objectives. Develop state-of-the-art technologies (platforms/devices) capable of diagnosing infectious disease and biological warfare (BW) agents in clinical specimens. The devices will be used by preventive medicine personnel for disease surveillance and monitoring, and by medical laboratory personnel for the diagnosis of disease due to natural and BW threat agents. Efforts will focus on an immunologically based membrane device to rapidly detect host immune responses to etiologic agents or the antigens or products of the agents themselves, and on miniaturized polymerase chain reaction technology for detection and identification of nucleic acids of natural infectious disease and BW agents.

Payoffs. The ability to quickly identify exposure to specific BW and infectious disease agents and rapidly treat warfighters is critical to maintaining the strength of the force and to giving commanders the ability to provide specific protective measures to yet unexposed warfighters. Many BW agent-induced illnesses have early symptoms that are flu-like and indistinguishable from each other and other less harmful pathogens. The ability to detect infection immediately after exposure would be extremely helpful in determining whether a BW attack has occurred and how many warfighters were exposed and in need of treatment. Early diagnosis is key to providing effective therapy. An effective broad diagnostic capability is important in locating the correct therapeutics and getting them moved in-theater in a timely manner. Collaborations with industrial/biotechnology entities, government, and academic centers of excellence will be developed to leverage continuing advances in biotechnology and industry. In FY99, an immunologically based membrane platform for malaria was transitioned to advanced development (program definition and risk reduction phase.) by the Military Infectious Disease Research Program.

Challenges. Challenges include development of rapid processing methods that can be used with a broad array of possible clinical specimens (i.e., whole blood, sputum, swabs, feces, and tissues); development of identification technologies and reagents of sufficient sensitivity and specificity to support early disease diagnosis; reduction of macro laboratory methods to portable devices; and development of rapid, automated specimen processing technologies. In addition, Indian rhesus nonhuman primates are required to evaluate and validate diagnostic approaches for the rapid for the rapid recognition of clinical disease, which is important performance data required for future FDA licensure. Constraints on this resource would impact the overall program schedule.

CB.27 Therapeutics Based on Common Mechanisms of Pathogenesis.

Objectives. Develop a suite of medical countermeasures against broad classes of biological pathogens (bacterial, viral, bioengineered, *etc.*) that share common mechanisms of pathogenesis.

Payoffs. Effective pathogen countermeasures may not eliminate the threat of biological warfare (BW) by a determined adversary, but they can provide a significant disincentive to its use. Program success will provide vaccine and therapeutic countermeasures that will reduce the threat of biological warfare and its operational impact through the development of new broad-spectrum antivirals and antibacterials. These will be particularly important for emerging and bioengineered threats for which there are no current countermeasures.

Challenges. The exploitation of modern genetic engineering by adversaries to develop "super pathogens" or to disguise agents is of concern. This emerging capability puts an even greater stress on our ability to detect and combat the medical consequences of exposure and infection. In addition, some potential operational environments could cause generalized immunosuppression, further increasing both the risk from biological threats and the need for robust immune defenses.

CB.28 Chemical Agent Prophylaxes II.

Objectives. Continue development (Phase 0) of a prophylactic that can detoxify nerve agents at a sufficient rate to protect the warfighter from exposure to up to five median lethal doses (5LD50) of nerve agents.

Payoffs. This technology objective would provide a capability for extended protection against a wide spectrum of nerve agents without causing side effects, behavioral effects, or the need for extensive post-exposure therapy. The successful application of this technology could reduce the reliance on mission-oriented protective posture gear by the warfighter.

Challenges. Major technical challenges include developing effective prophylactics devoid of side effects, developing circulating scavengers with extended half-lives, developing suitable animal models for these studies, producing sufficient material for safety and efficacy studies, and extrapolating efficacy test results from animals to man.

CB.29 Active Topical Skin Protectant.

Objectives. Increase the protection offered by the Skin Exposure Reduction Paste against Chemical Warfare Agents (SERPACWA), the licensed topical skin protectant (TSP), by incorporating an active moiety that will neutralize nerve agents and sulfur mustard. This active moiety must be compatible with SERPACWA and not be irritating to the skin.

Payoffs. Nerve agents and sulfur mustard are significant threats to U.S. forces. While pretreatment and treatment compounds are available for nerve agents, no specific countermeasure has been developed for sulfur mustard. An active TSP would either augment the protection afforded by the protective overgarments or, ideally, redefine and reduce the circumstances requiring mission-oriented protective posture levels. The rapid action of sulfur mustard suggests that a pre-exposure skin protection system offers the best opportunity to prevent the serious consequences from percutaneous exposure to this agent. This approach also reduces the risks from skin exposure to nerve agents. An effective active TSP would deter the use of chemical agents by an enemy and increase the ability of U.S. and allied forces to sustain operational tempo.

Challenges. Major technical challenges include: (1) developing active moieties that are not irritating to the skin, (2) developing active moieties that are catalytic and not limited by stoichiometry, (3) developing suitable evaluation models, and (4) extrapolating efficacy test results from animals to humans.

CB.30 Medical Countermeasures for Vesicant Agents II.

Objectives. Demonstrate a safe and effective pharmacological countermeasure to prevent or decrease by 80% the severity of blister injuries caused by vesicant chemical agents, focusing principally on sulfur mustard. Compounds or combinations of compounds will be evaluated against one another to determine the best therapy for transition to advanced development.

Payoffs. Currently, medical management of the injuries produced by blister agents is limited to immediate decontamination followed by conventional treatment of the resulting blisters or burns. This work will yield a vesicant agent countermeasure that will substantially reduce the degree of injury among exposed soldiers, with concomitant reductions in the medical logistic burden.

Challenges. Challenges include developing therapeutic measures with minimal adverse effects, demonstrating safety and efficacy, developing formulations, and extrapolating test results from animals to humans.

CB.31 Medical Countermeasures for Brucellae.

Objectives. Develop medical countermeasures for Brucellae. Specifically, develop a genetically characterized live, attenuated vaccine that elicits cellular and humoral immunity against the four pathogenic species of Brucella and protects 90% of individuals against disease after aerosol challenge.

Payoffs. *Brucella melitensis, B. abortus*, and *B. suis* are closely related validated biological warfare threat agents that are highly infectious by aerosol and cause severely incapacitating illness. B. canis can also cause disease, but is less threatening. Protective strategies that rely on antibiotic prophylaxis or treatment may not be adequate: a multi-drug resistant strain of *B. abortus* is known to exist. Live attenuated vaccines have proven highly successful in controlling brucellosis in livestock, but none is suitable for human testing. A candidate live, attenuated vaccine developed by USAMRMC between 1993 and 1999 is attenuated in mice and non-human primates (NHP) and highly efficacious in a pulmonary challenge model in mice. A vaccine that is efficacious against aerosol challenge in NHPs should protect humans against infection with all pathogenic species of Brucella. Such a vaccine would benefit warfighters at risk of exposure to this biological threat agent. Additionally, a live, attenuated Brucella vaccine may have future value as a vector to deliver antigens to protect against a number of biological threat agents.

Challenges. Major technical challenges include defining the most appropriate in vitro correlates of protective immunity, and defining the best criteria for demonstration of efficacy. The limited availability of nonhuman primates for research also presents a challenge.

CB.32 Needle-less Delivery Methods for Recombinant Protein Vaccines.

Objectives. Develop alternatives to the injection of recombinant protein-based vaccines that result in mucosal and systemic immunity to these agents.

Payoffs. Significant mortality and morbidity are associated with inhalation exposure to threat agents such as staphylococcal enterotoxins (SE), Bacillus anthracis (anthrax), and Yersinia pestis (plague). Protection against lethality is considered a minimal requirement of a medical countermeasure. Recombinant proteins that have been used as vaccine antigens are available for each of these agents and studies in rhesus monkeys demonstrate the parenterally administered vaccines are effective against an inhalational challenge. SEs are also incapacitants in human subjects. Although parenterally administered SE vaccine candidates protected rhesus monkeys from lethal SE type B challenges, a number of the animals experienced incapacitating signs after toxin challenge. Existing data suggest mucosal and systemic immunity are required to prevent lethality as well as incapacitation caused by SE exposure. Mice immunized intranasally with SE vaccines were protected from inhalation and intraperitoneal toxin challenges and demonstrated levels of mucosal antibodies significantly higher than in mice immunized intramuscularly. A mucosal respiratory immune response may improve vaccine efficacy by providing immunity at the portal of agent entry. Potential CRADA partners have been identified that can share expertise in technologies for delivery of biological factors. This will facilitate rapid transition of candidate products. Needle-less administration of vaccines avoids health risks involved with the use of needles. Intranasal, transdermal, inhalation, or oral immunization strategies may be safer and more efficacious methods for stimulating mucosal and systemic immunity. These strategies will be useful for the administration of a significant number of vaccines currently planned to obtain total force protection.

Challenges. Major technical challenges include defining quantifiable immunological end-points indicative of protection, producing stable vaccine formulations, selecting practical and efficacious route(s) of administration, and protecting vaccinated individuals from lethal and incapacitating toxin challenges.

CB.33 Recombinant Protective Antigen Anthrax Vaccine Candidate.

Objectives. Characterize (biochemically and immunologically) a recombinant protective antigen (rPA) anthrax vaccine, including preliminary development of an appropriate *in vitro* correlate of PA-induced protective immunity against Bacillus anthracis aerosol exposure.

Payoffs. This vaccine candidate should facilitate the characterization of the major protective component of Anthrax Vaccine Absorbed (AVA) and will provide the basis for a next generation anthrax vaccine suitable for licensure by the FDA. Preliminary efficacy experiments in a rabbit model have already demonstrated that protection is afforded by rPA produced from either *B. anthracis* or *E. coli*. To date, an in vitro correlate in humans to vaccine-induced immunity against anthrax does not exist. Circulating anti-PA antibody from mice, rabbits, or monkeys can be evaluated as a surrogate marker for efficacy by passive immunization followed by aerosol challenge, to determine if the animals are protected. Demonstrating proof-of-concept for anti-PA antibody as a surrogate marker should facilitate development of an assay for predicting protective immunity in humans after immunization with rPA. Definition of a surrogate marker will facilitate FDA licensure of the vaccine candidate.

Challenges. Challenges are to expand animal efficacy studies comparing AVA with rPA, and demonstrate surrogate efficacy against *B. anthracis* aerosol challenge with antibody to rPA alone.

CB.34 Recombinant Plague Vaccine.

Objectives. Complete the pre-clinical development of the recombinant F1-V fusion protein plague vaccine candidate.

Payoffs. Infection induced by inhalation of *Yersinia pestis* represents a serious biological warfare threat. The resultant disease, pneumonic plague, is associated with an incubation period of 2–5 days and an untreated mortality of nearly 100% within 1–3 days after onset of illness. The previously licensed plague vaccine is no longer available and provides poor protection against aerosolized *Y. pestis*. The recombinant F1-V fusion protein has shown excellent protection against aerosolized *Y. pestis* in rodents and partial protection in a preliminary non-human primate (NHP) study. Additional preclinical studies in animals will be required to define optimal dosing schedules, long-term immunogenicity, and duration of protection. Additionally, *in vitro* correlates of protective immunity must be established for FDA licensure. A strong correlate of immunity with an associated assay could potentially replace older animal-based efficacy testing for vaccine potency. The vaccine candidate should also be assessed against a variety of strains of virulent *Y. pestis*. Well-established mouse and non-human primate aerosol models will facilitate completion of these goals. An effective FDA-licensed vaccine against aerosolized plague will enhance force protection and strategic mobility.

Challenges. Major technical challenges include identification of the most appropriate in vitro correlates of protective immunity against aerosolized plague, establishment of a surrogate efficacy model for F1-V immunity, and the time required to assess the duration of protection offered by the F1-V vaccine candidate.

CB.35 Standoff Biological Aerosol Detection.

Objectives. Develop and demonstrate technology by the end of FY04 for an advanced, wide-area, standoff biological detection capability to both detect and discriminate biological aerosol clouds at operationally significant concentrations.

Payoffs. This DTO addresses JSIG JFOC Contamination Avoidance: Biological Early Warning. The development of this technology would permit the rapid detection, discrimination, and location of biological aerosol clouds. This technology would also be capable of being used on various platforms for the purpose of air or ground biological reconnaissance and contamination avoidance. Technology developed under this effort is intended to address operational requirements of the Joint Biological Standoff Detection System, for which essential target parameters are a range (threshold) of 25 km, sensitivity (threshold) of 15 agent-containing particles per liter of air (ACPLA), and real-time detection. In FY01, several potential technology solutions were identified and the initial downselect was completed with user input. Some technologies under consideration include imaging (UV, near IR, long-wave IR), millimeter-wave, and polarization (UV, IR) spectroscopy.

Challenges. Significant progress has been made recently in both active and passive standoff detection arenas with respect to biological detection. Despite this, significant challenges remain. In addition to size, weight, and power, challenges exist with respect to both sensitivity and specificity leading to hybrid technology concepts (use of two or more technologies) for the final system design.

CB.36 Universal End-of-Service-Life Indicator for NBC Mask Filters.

Objectives. Develop a low-cost, universal end-of-service-life indicator (ESLI) for use in NBC protective mask filters that will indicate the presence of a broad range of chemical warfare agents and toxic industrial chemical vapors/gases. This will be achieved through an extensive technology survey, identifying best candidate solutions, developing an ESLI design concept, and demonstrating the efficacy of the design concept with target challenge agents.

Payoffs. This DTO addresses JSIG JFOC Individual Protection: Respiratory/Percutaneous. Presently there are no means to determine the residual life of fielded filters. Development of a universal ESLI will greatly enhance serviceman safety by alerting the user to replace the filter before its gas life capacity has expired. Other benefits include reduced cost and logistical burden since current change-out doctrine is conservative and results in the premature replacement and excess stockpiling of filters in the field. This DTO addresses a desired requirement for the Joint Service General Purpose Mask. The ESLI technology developed in this effort will also have direct application to commercial respirator filters used in the workplace as well as other dual-use applications such as residual life indicators for collective protection filters and chemical protective clothing. In FY01, several color-changing passive (nonpowered) technologies were identified and screened against representative chemical agent, simulant, and toxic industrial organic vapors and acid gases; and screening of two alternative candidate general-indicator technologies, mettaloporphyrins and polymerized diacetylenes, was initiated.

Challenges. Development of a "universal" colorimetric ESLI to detect such a wide range of contaminants is considered moderate to high risk. Although state-of-the-art passive technologies such as colorimetric indicators exist for detecting specific contaminants, most rely on specific reaction chemistry and, thus, are not suitable as universal (i.e., multi-contaminant) indicators. Realistically no single indicator is expected to achieve such nonspecificity; however, it is feasible that a combination of different nonspecific colorimetric indicator technologies could be used to target key organic vapor and acid gas contaminants of concern. This DTO will focus on passive indicator technologies capable of detecting a select range of key chemical warfare and toxic industrial agents.

CB.37 CB Agent Water Monitor.

Objectives. Develop system concepts and technologies to meet the service requirement for a Joint Chemical Biological Agent Water Monitor. The desired capability is for the detection and identification of hazardous chemical and biological agents in potable water. The system will be capable of processing both source (ponds, lakes, rivers, *etc.*) and treated water (purified and distribution systems). It is unlikely that a single technology will be able meet this objective. Therefore, the system will most likely consist of two or more integrated technologies that have been optimized to meet a specific challenge.

Payoffs. This DTO addresses JSIG JFOC Contamination Avoidance: Medical Surveillance. The only system currently fielded for the detection of agents in water is the M272 Water Test Kit. This kit has several drawbacks, including an inability to detect biological agents and a relatively long response time. This kit is difficult to use when in a protective posture and is incapable of autonomous operation, requiring a user to interpret the results. The water monitor developed in this effort will be capable of detecting both chemical and biological agents. In addition, it will be capable of real-time, autonomous operation, which will allow the system to be used as a true water monitor. In FY01, development of standardized test evaluation protocols ws completed and the testing of technologies was initiated. Transition criteria were established based on JCBAWM Operational Requirements Document (ORD). A first-generation design for water monitor system was completed and the breadboard build was initiated.

Challenges. The challenges associated with this DTO are numerous. The system will be required to operate under a variety of environmental conditions, ranging from extremely turbid source water to chemically treated "clean" water. Experience shows that this will pose a significant challenge in terms of both agent sensitivity and specificity. The system will also be required to operate in near real time (less than ten minutes). While this may or may not be a significant factor for chemical agents, it is extremely challenging for biological agents. Current biological detection technologies rely on analytical techniques, which range in processing times from hours to days. Sensitivity requirements also pose a significant challenge. In addition, an understanding of the actual threat in water is not clear. Chemical agents, for instance, undergo chemical changes in water much more quickly than in air. Factor such as hydrolysis will be significant. Biological agents will no doubt undergo changes as well, making the detection problem somewhat dynamic.

CB.38 Activity-Based Detection and Diagnostics.

Objectives. Demonstrate engineering of cells and tissues that is directed toward the development of activity detection systems for biological and chemical threats, and develop metrics for system performance in detection applications to include environmental sensing and advanced diagnostics for critical defense needs.

Payoffs. The successful demonstration of cell and tissue activity detection systems could provide dramatic new capabilities for sensing the activity of existing, emerging, and engineered biological and chemical warfare threats or hazards. These detection systems could also be used as monitors for toxins related to operational exposures in deployment toxicology and could provide rapid surveillance tools for epidemiologic surveillance of environmental or medical samples. Successful demonstration of cell- and tissue-based detection systems could also be used as high-throughput screening tools for drug discovery.

Challenges. The program approach is based on robust extraction of cell and tissue signatures of agent response. The first task will focus on the generation of these signatures and the use of pattern recognition tools to robustly extract signatures of activity and response. This task will also include the reduction of critical risk parameters associated with the design and fabrication of working prototype cell- or tissue-based activity detectors. These include sample collection and preparation, extended cell and tissue performance and shelf life, optimized fluidics, and data acquisition and analysis tools. The second task is dedicated to testing and validating the system prototypes that include hand-held and small footprint benchtop systems. The most significant issues that must be addressed are: (1) Cell/Tissue Response and System Prototype Development--populate library of key cell and tissue responses to chemical and biological agents of interest to DoD that could be monitored in environmental and diagnostic samples; demonstrate extended performance of cells and tissues to enable the recording of agent response for an operationally relevant timeframe (21days); and develop a sample collection and preparation module suitable for cell and tissue detector systems threats; (2) System Testing and Validation--incorporate cell/tissue signatures into prototype systems; test and validate prototype detection systems; and develop metrics for specific operational use.

CB.39 CW/BW Agent Screening and Analysis.

Objectives. Provide the technology required to meet DoD requirements under CWC and BWC: (1) Agent and Byproduct Extraction--effectively and rapidly isolate of target compounds from treaty-obtained environmental samples; (2) Agent and Byproduct Screening Technology--develop hand-held real-time, simple-to-operate screening methods for field operations; (3) Agent and Byproduct Determinative Analysis--increase equipment throughput and speed, improve instrument portability and ruggedness, and develop target compound-specific instrumentation not otherwise required by industry; and (4) Remote and Nondestructive Evaluation Techniques--develop highly portable, noninvasive interrogation methods for agents and byproducts within containers of all shapes and configurations.

Payoffs. This DTO promotes national security and protect confidential business information while implementing arms control treaties in the most cost-effective manner. Current technologies and infrastructure are not timely and sufficiently cost effective to protect U.S. equities.

Challenges. Current technology equipment size, portability, and detection limits do not meet the desires of U.S. policy makers. These technologies must also be developed in such a manner that ITAR requirements and reciprocity concerns are alleviated.

CB.40 Immune Building Program.

Objectives. Develop and demonstrate technologies and systems to allow military buildings to actively respond to attack by agents of chemical or biological warfare so as to (1) protect the human occupants from the lethal effects of the agent, (2) restore the building to function quickly after the attack, and (3) preserve forensic evidence about the attack.

Payoffs. Enabling buildings to respond actively, in real time, to the presence of threat agents will not only greatly reduce the effectiveness of such attacks, but will also make the buildings less attractive as targets.

Challenges. These objectives will be achieved through a mix of passive and active modifications and augmentations to building infrastructure. ``Passive`` modifications are those in use continually and include, for example, highly efficient filtration; ``active`` augmentations are those used only in the presence of the threat and include real-time control of airflow or real-time neutralization of aerosolized agent. Active response requires networked surveillance systems. Such systems require the development of a number of component technologies in areas like filtration, neutralization, and decontamination. In addition, the implementation of a complex system of this type requires that a number of systems-level issues be resolved, including the design, implementation, and optimization of systems architectures. As proof that all issues have been appropriately addressed, the program will conclude with a full-scale demonstration of a functioning system at a military installation.

CB.41 Biological Warfare Defense Sensor Program.

Objectives. Develop a fully integrated, well-characterized sensor system for the effective real-time detection of biological warfare (BW) agents to enable pre-exposure detection and discrimination.

Payoffs. This DTO will provide military personnel with advanced warning of specific active exposure to BW agents, and an "all clear" assessment after the use of appropriate decontamination/neutralization countermeasures.

Challenges. The critical challenge is to produce sensor systems that are sufficiently fast and selective to permit an accurate low-false-alarm, high-probability-of-detection decision to be made in a sufficiently timely manner to permit proactive protection of military personnel. As part of accomplishing this task, the fabrication of the first-generation automated time-of-flight mass spectrometer and its characterization for a limited number of BW agents and backgrounds will be completed in FY01. In FY02, the characterization will be extended to more species and strains of threat agents, and the optimization of the system to minimize the false-alarm rate will be investigated.

CB.42 Environmental Fate of Agents.

Objectives. Develop a validated threat agent fate model that is capable of accurately predicting the persistence of a chemical agent dispersed on surface materials relevant to fixed site operational scenarios.

Payoffs. This DTO addresses JSIG JFOC Battle Management: Battle Management Analysis; establishes challenge levels and protection factors necessary for multi-service operating environments based on validated datasets and consistent analytical methodology; and develops a science-based model validated against laboratory studies and field testing to reduce uncertainty for predicting chemical threat agent fate and persistence. Such a model, when based on "first principals" rather than simple empirical methods, serves as a master template for addressing persistence analysis for future novel chemical and biological threat agents. Results of this program will directly support numerous decision tools such as the Joint Effects Model (JEM) and Joint Operational Effects Model (JOEF).

Challenges. Formulation, standardization, and dispersing techniques for thickened agents are major technical hurdles. Establishing a valid model that allows prediction before an observation, while not new in concept, has rarely been pursued as an end product.

CB.43 Chemical and Biological Warfare Effects on Operations.

Objectives. Develop a general-purpose model of the operations of large fixed-site facilities (air bases, aerial ports of debarkation (APODS), and seaports of debarkation (SPODS)), with the capability to represent chemical and biological warfare (CBW) attacks and their operational impacts.

Payoffs. The model will assess the operational impact of CBW attacks on fixed-site targets which are particularly susceptible to CBW attacks, significantly degrading their output, and hampering combat operations. It is intended as both an interactive and distributed tool, filling an important gap in the DoD modeling and simulation toolset. In wargaming simulations, the model will receive tasking inputs from its operators or the other simulations and generate corresponding degrades after an attack. It would alert the theater wargame model of the mission results and determine the disposition of assets on the mission, track surviving assets, and model asset turn around for other missions. The model will provide wargaming support for APODs, SPODs, depots and other fixed-site facilities. In studies, it can be used to assess the feasibility of base operations in a given CBW scenario, responding to the postulated threat and the defensive capabilities of a selected base. Operational planners can determine best trade-offs for base assets, work degradation, and relocation options. Newly fielded hardware/defensive capabilities (equipment procurement, detector deployment or modified CONOPS) can be assessed in terms of increased sortie rate or reduced casualties. The model will help determine the best mix of CBW defense capabilities and the most effective acquisition strategy.

Challenges. Obtaining datasets that are complete, accurate, and representative for each contemplated use of the model is the most significant challenge. Validating model results with real-world results of CBW operational exercises is difficult because data are extremely limited. Data collection is time consuming and costly. Support of controlling organizations is frequently necessary, not only in making the data available, but also in its reduction, interpretation, and conversion to usable formats. In some cases the data will have to be obtained through experimentation, such as the effect of wearing next-generation CBW protective equipment and performing typical tasks. Other challenges include developing methodology for APODs/SPODS and increasing model execution speed sufficiently for wargaming environments.

CB.44 Oxidative Decontamination Formulation.

Objectives. Develop a non-corrosive, material compatible, nontoxic and environmentally oxidative chemical/biological decontaminant to replace DS2 and STB/HTH.

Payoffs. This DTO addresses JSIG JFOC Restoration Capability: Equipment/Facilities/Large Area. An oxidative formulation will be effective against standard CWAs, FGAs and biological agents. Since this effort uses a formulation approach, it will allow for the incorporation of enzymes and polymeric catalysts (DTO CB.09), a DARPA-developed biological decontamination solution, and other reactive technologies into one formulation with a peroxy-based oxident serving as the primary reactive component. Multiple reactive components in a pH range of 7.5-9.0 will allow oxidation or displacement reactions that yield acceptable reaction products. Water-soluble components and simple in situ mixing will make the formulation compatible with existing military or COTS decontamination applicators.

Challenges. Reactivity, pot life, and long-term storage requirements are significant challenges. In addition, compatibility of formulation components may be an issue. In order to reduce the logistical burden, appropriate packaging must be well thought out. Leveraging off of industry expertise will greatly reduce potential risk in these areas.

CB.45 Self-Detoxifying Materials for Chemical/Biological Protective Clothing.

Objectives. Incorporate agent reactive catalysts and biocides directly into chemical/biological (CB) protective clothing and demonstrate their capability to self-detoxify.

Payoffs. This DTO addresses JSIG JFOC Individual Protection: Respiratory/Percutaneous. This DTO will provide an increased level of protection to CB protective clothing through the added capability of self-detoxification. Agent reactive catalysts and biocides will neutralize chemical/biological wafare (CW/BW) agents on contact, resulting in increased protection and a substantially reduced hazard when donning and doffing as well as disposing of contaminated clothing.

Challenges. The addition of agent reactive catalysts and biocides to advanced CB clothing systems must strike a balance between the added capability provided and the extra weight added to the garments. Since CB clothing is burdensome to wear, any extra weight must result in additional benefit to the warfighter. In this case, the additional benefit is increased protection. Agent reactive catalysts are specific in their behavior. Catalysts have been developed which are effective against mustard, for example, while other catalysts have been shown to be effective against nerve agents. It is not practical at this time to expect universal agent neutralization. In general, biocides are more universal in their activity.

BE.10 High-Resolution Meteorological Nowcasting for Chemical/Biological Hazard Prediction.

Objectives. Develop a high-resolution local, regional, and global atmospheric prediction system that describes and forecasts/nowcasts battlespace environment (BSE) parameters to support prediction of the fate of chemical and biological agents, smoke, toxic industrial materials, and other agents in the environment for all DoD applications; and incorporate these BSE parameters into improved chemical/biological (CB) dispersion models to more accurately describe dispersion under a wider range of atmospheric conditions (night time, stable, in complex terrain, at high altitudes, etc.,) than current capabilities. This DTO matures emerging basic research (6.1) for direct applications to the Service (6.4) users.

Payoffs. Atmospheric conditions have a first-order effect on the dispersion, deposition and fate of CB agents in the battlespace environment. Current operational atmospheric observation and prediction systems do not have sufficient resolution, speed, geographical coverage, or altitude range needed to provide a robust, accurate, validated operational capability to predict the effects of chemical and biological agents over the range of militarily significant time and space scales. The lack of near-real-time high-resolution weather support means that fast response hazard predictions essential for contamination avoidance, protective posture, and consequence management have high uncertainty at the time they are most critical, i.e., at the time of an incident and shortly thereafter. Deficiencies in atmospheric modeling systems will be addressed by: increasing vertical resolution near the surface and at high-altitudes (i.e., above 30 km for theater ballistic missile threat applications); improving dispersion physics near the surface under stable night time conditions and in complex terrain; assimilating on-scene observations into mesoscale forecasting systems; increasing resolution and parameterization of radiation, turbulence, and precipitation physics; and utilizing high-resolution surface and terrain data. CB dispersion models will be improved by investigating methodologies that more accurately represent turbulent fluctuations, and will be coupled to atmospheric models in a physically realistic (thermally and dynamically) manner. A set of best engineering and operational practices will be developed, and the modeling system will be verified and validated for a realistic range of applications.

Challenges. In the coupled (meteorological and dispersion) system, the primary challenge lies with the representation of realistic mesoscale meteorological fields in a consistent fashion at the appropriate scales. A multisensor/multiscale approach is required in order to provide localized, on-scene weather information at tactical-scale spatial resolution. Additionally, as time-critical decisions are necessitated, the forecast capability should be tied to real-time observational nowcast and battlefield management systems (currently in development) for executing and managing prudent operations in the battlespace. Improved modeling of high-altitude and near-surface atmospheric physics and agent behavior, especially in environments containing interferents such as smoke, fog, and dust, will require significant effort to validate. Considerable effort needs to be conducted on the operational test and evaluation of the capability, exercise support, and development of concepts of operations, tactics, techniques, and procedures.

L.07 Terrorist Chemical/Biological Countermeasures.

Objectives. Develop effective countermeasures for detecting and identifying chemical/biological (CB) agents and toxic industrial chemicals (TICs) deployed in terrorist weapons.

Payoffs. The development of enhanced countermeasures will improve the capabilities of military and civilian units responding to terrorist threat incidents.

Challenges. The key challenge is to develop lightweight systems to reliably detect and identify a wide range of CB and TIC threats in an urban environment, while overcoming system complexity, operability, and affordability issues.

L.12 Force Medical Protection/Dosimeter ACTD.

Objectives. Develop an individually worn environmental sampler that can continuously measure and archive chemical and biological agent exposures. Phase I development will emphasize passive collection and archiving of chemical agent exposures and non-real-time chemical analysis. Phase II development will emphasize real-time alarming for chemical agent exposures and individual, active collection and archiving of biological agents for non-real-time analysis. An extensive concept of operations (CONOPS) encompassing diverse operational forces and scenarios will also be developed.

Payoffs. Improved detection and identification capabilities will provide greater awareness of immediate chemical exposure risk and more precise identification of exposures across a boarder range of agents. The architecture for routine monitoring and analysis will improve risk assessments and record keeping. Additional payoffs will include the communication of exposure information to command centers and increased battlefield awareness and intelligence. This ACTD leverages activities in the Terrorist Chemical/Biological Countermeasures program and DARPA efforts in pathogen detection/identification.

Challenges. Specific challenges include developing technologies to collect, analyze, and differentiate between agents, interferents, and naturally occurring compounds; and improving selectivity and sensitivity to agents. Providing communications capabilities and real-time alarm while reducing size and weight will require advances in sampling methods, chemical analysis techniques, and electronics. Developing a CONOPS to include use of a sampler will require modeling, experimentation, and field testing to improve capabilities and increase utility.